UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re CELGENE CORPORATION SECURITIES LITIGATION	Civil Action No. 18-cv-04772 (MEF) (JBC) **FINAL PRETRIAL ORDER** JURY TRIAL DEMANDED

This matter having come before the Court for a pretrial conference pursuant to Fed. R. Civ. P. 16; and James E. Cecchi, Matthew L. Mustokoff, Margaret E. Mazzeo, Jamie M. McCall, Nathan A. Hasiuk, Salvatore J. Graziano, Adam H. Wierzbowski, Robert F. Kravetz, and Aasiya F. Mirza Glover having appeared for Lead Plaintiff and Class Representative AMF Tjänstepension AB ("AMF" or "Plaintiff") and the certified Class, and Lawrence S. Lustberg, Kate E. Janukowicz, Robert C. Micheletto, Nidhi Yadava, Rajeev Muttreja, Sarah D. Efronson, Andrew B. Clubok, Michele D. Johnson, Susan E. Engel, and Kevin M. McDonough having appeared for Defendants Celgene Corporation, Terrie Curran and Philippe Martin; the following Final Pretrial Order is hereby entered:

I. JURISDICTION (set forth specifically).

1. Plaintiff's claims arise under Sections 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5 promulgated thereunder. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

II. PENDING/CONTEMPLATED MOTIONS (Set forth all pending or contemplated motions, whether dispositive or addressed to discovery or to the calendar. Also, set forth

the nature of the motion and the return date. If the Court indicated that it would rule on any matter at pretrial, summarize that matter and each party's position).

There is one pending motion: Defendants' Motion to Bifurcate Trial (D.E. 352). The parties' contemplated motions consist of the following:

A. Plaintiff:

1. Motion to bifurcate the trial into two phases—one that addresses common class-wide issues (including Defendants' liability and the measure of class-wide per-share damages) ("Phase One"), and, if necessary, a second phase that addresses class member-specific individualized issues ("Phase Two"), and, as a result to preclude any reference, evidence or argument concerning:

a. individualized reliance issues (including as to AMF and its representatives) or anything relating to individualized issues in the Phase One trial;

b. the Class's or AMF's actual or estimated aggregate damages;

c. AMF's trades in Celgene, AMF's individual investments, investment decisions, investment strategies, and/or history with respect to Celgene or non-Celgene securities or investments;

d. the absence of representatives of AMF testifying at the trial;

e. AMF's retention, portfolio monitoring, or attorneys' fee arrangements;

f. AMF's selection of counsel;

g. AMF's size, assets under management, financial condition or alleged sophistication;

h. AMF's residence or location or the characteristics of any individual Class members;

i. AMF's or its counsel's political contributions;

j. AMF's or its counsel's involvement in other litigation;

2. Motion to exclude any reference, evidence, or argument regarding irrelevant and prejudicial post-Class Period events, including any reference, evidence, or argument about:

a. the features of Otezla that made it suited to help patients during a pandemic;

b. Otezla's post-Class Period sales and revenues, patient feedback or other performance or commercial or medical success;

c. any new medications that came into existence after the end of the Class Period and that do not concern or relate to information in Defendants' possession during the Class Period or statements made by Defendants during the Class Period; and

d. the circumstances of Bristol-Myers Squibb's acquisition of Celgene or Amgen's acquisition of Otezla, including:

i. the price Bristol-Myers Squibb paid to acquire Celgene or that Bristol-Myers Squibb's acquisition of Celgene is in any way an indication or testament to the supposed success, propriety and/or honesty with which Celgene conducted and/or ran its business prior to being acquired; and

ii. the price paid by Amgen for Otezla, Otezla's sales and revenues generated post-acquisition, or otherwise arguing about the commercial or medical success of the drug after Amgen's acquisition.

3. Motion to exclude certain irrelevant reference, evidence, or argument concerning:

a. Celgene's, Bristol-Myers Squibb's, and any former Celgene employees' (including Defendant Curran's and Defendant Martin's) alleged good works, commitment to patient safety, life-saving efforts or products, non-relevant scientific research and development efforts or expenditures, charitable contributions, and/or character;

b. the number of persons that Celgene employed, or the size of its operations prior to and during the Class Period, including in New Jersey, and the same for Bristol-Myers Squibb since the Class Period and currently;

c. the effect that a judgment for the Class might have on Bristol-Myers Squibb or Defendants Curran and Martin, the ability of patients to purchase or have available medications, the cost of medicine or insurance, the viability of the pharmaceutical industry, or that a judgment against Defendants may result in layoffs, financial or personal hardships, or people losing their jobs; and

d. any purported "litigation crisis," "lawsuit crisis," "lawsuit abuse," "lawyer driven litigation" or similar terms or phrases, or attacks on the integrity of Plaintiff's counsel or references to the conduct of Plaintiff's counsel unrelated to this litigation.

4. Motion to preclude argument denigrating AMF due to its status as a foreign pension fund.

5. Motion to preclude reference, evidence or argument concerning (i) allegations in any complaint filed in this action, including the Second Amended Complaint or Third Amended Complaint, (ii) the fact that any claims, legal theories, or defendants have been dismissed from this Action and (iii) any claims or legal theories that Plaintiff has abandoned and/or modified.

6. Motion to preclude reference, evidence or argument concerning any affirmative defenses not asserted in Defendants' Answer, including any evidence or argument regarding reliance on counsel or outside accountants.

7. Motion to preclude reference, evidence or argument that Ms. Betty Jean Swartz was terminated from her employment at Celgene or regarding the circumstances of her departure.

8. Motion to preclude reference, evidence, or argument that Ozanimod is efficacious or safe as irrelevant to the alleged misrepresentations and omissions about Ozanimod made by Defendants in 2017 and 2018.

9. Motion to preclude reference, evidence, or argument regarding AMF's alleged loss of evidence from personnel who had roles regarding AMF's investment decision-making.

10. Motion to preclude reference, evidence, or argument that Defendants' statements related to Otezla or Ozanimod were forward-looking, accompanied by meaningful cautionary language, or otherwise protected under the PSLRA's safe harbor for forward-looking statements.

11. Motion to exclude the summary judgment declaration of Defendant Terrie Curran and to preclude reference, evidence, or argument concerning the declaration.

12. Motion to preclude reference, evidence, or argument that Defendants did not violate Section 10(b) or Rule 10b-5 because the Ozanimod rNDA was ultimately approved by the FDA.

13. Motion to depose Defendants' trial witnesses who were not been deposed during fact discovery, including Maria Palmisano, Gondi Kumar, Russell Katz, and Marcie Wood.

14. Motion regarding the introduction and scope of deposition designations pursuant to Federal Rule of Civil Procedure 32.

15. Motion to govern trial procedures, including:

a. to sequester or exclude non-party fact witnesses from the courtroom (except while testifying) during trial, and to preclude these same witnesses from reading transcripts or discussing the proceedings with Defendants or Defendants' counsel or their agents while the trial is in progress;

b. to permit leading questions of a hostile witness, an adverse party, or a witness identified with an adverse party;

c. to re-call Plaintiff's Document Reader as needed throughout the trial; and

d. to preclude the parties, their counsel and their agents from speaking with any witnesses while the witnesses are under examination.

16. Plaintiff also anticipates filing motions to limit or preclude portions of Defendants' experts' testimony as described below in Section IX.D.

B. Defendants:

1. Motion to dismiss AMF's asserted Ozanimod claims and de-certify Plaintiff as class representative for Plaintiff's Ozanimod claims because Plaintiff, having not purchased any shares of Celgene stock prior to any of Plaintiff's remaining alleged misstatements or omissions related to Ozanimod following the Court's summary judgment ruling, *see* Dkt. No. 310, lacks standing to pursue its Ozanimod claims and is not an adequate class representative, and/or a motion to re-open discovery to seek documents and testimony regarding AMF Fonder AB's purchases and investments in and related to Celgene securities and the purported assignment to Plaintiff of AMF Fonder AB's alleged claim in this action.

2. Motions to exclude certain irrelevant reference, evidence, or argument concerning:

a. The Individual Defendants' assets or wealth;

b. Agreements, policies or other arrangements providing liability coverage or indemnification to any Defendant;

c. The fact that certain witnesses were former defendants in this lawsuit;

d. The fact that certain witnesses are currently employed at the same organization and may have provided assistance to one another in retaining those employment positions;

e. The current financial condition of Celgene or Bristol Myers Squibb ("BMS");

f. The identification of the Ozanimod metabolite prior to June 2017;

g. The alleged falsity of corporate statements that did not survive dismissal or summary judgment;

h. References to "Big Pharma" or similar pejorative terms to describe Celgene, BMS or the pharmaceutical industry generally;

i. The April 2018 Morgan Stanley report as an alleged corrective disclosure for Ozanimod;

j. Statements made by Peter Kellogg and Steven Rosen regarding Wall Street's expectations for Otezla;

k. The expiration or anticipated expiration of the Revlimid patent, agreements for generic sales of Revlimid, and Celgene's revenue attributable to Revlimid;

l. The discontinuance of development of GED-301;

m. The price difference between brand-name and generic drugs;

n. Sales of generic versions of Gilenya as a motive for the alleged misleading statements regarding Ozanimod;

o. Curran's knowledge about Otezla post-dating her July 2017 statement, including the suggestion that such knowledge is evidence of what Curran knew before her July 2017 statement;

p. Curran's knowledge about Otezla post-dating her April 2017 statement as evidence of what she knew about market share prior to the April 2017 statement;

q. The compensation, including bonuses and other incentive compensation, that Defendants and other Celgene personnel received or could have received from Celgene;

r. Any suggestion that the FDA's guidance constitutes binding requirements and obligations;

s. Evidence related to AMF Fonder and its assignment of claims in this case.

3. Motions to govern trial procedures, including a motion:

a. To issue a jury instruction that Martin's scienter is not a basis for determining whether Celgene made any statements with scienter;

b. To issue a jury instruction regarding forward-looking statements and the Private Security Litigation Reform Act's ("PSLRA") safe harbor, *see* 15 U.S.C. § 78u-5(c);

c. To issue a jury instruction regarding application of the corporate scienter doctrine;

d. To issue a jury instruction regarding Plaintiff's spoliation of relevant evidence regarding its decision to invest in Celgene from two of its key employees in charge of its investment decisions: its Chief Investment Officer, Javiera Ragmarez, and its North America portfolio manager, Ulf Forsberg.

4. Defendants also anticipate filing motions to exclude or preclude all or portions of anticipated testimony from Plaintiff's proposed expert witnesses as described below in Section IX.B.

III. STIPULATION OF FACTS (Set forth in narrative form a comprehensive listing of all uncontested facts, including all answers to interrogatories and admissions, to which there is agreement among the parties).

1. Celgene, a Delaware corporation headquartered in New Jersey, is a biopharmaceutical company.

2. In 2017 and 2018, the Company operated two primary divisions: (i) the Inflammation & Immunology (I&I) franchise, which focused on drugs for treatment of

inflammatory diseases, such as psoriasis (PsO), psoriatic arthritis (PsA), ulcerative colitis (UC), multiple sclerosis (MS), and Crohn's disease (CD); and (ii) the "Hematology & Oncology" franchise, which focused on treatments for blood diseases and cancer.

3. During the Class Period, Celgene's common stock traded on the NASDAQ Global Select Market under the ticker symbol "CELG."

4. Scott Smith was the President of Celgene I&I and the Chairman of the Inflammation and Immunology Executive Committee ("IIEC") from 2010 until April 2017.

5. From March 2016 through April 1, 2017, Terrie Curran served as President of Worldwide Markets for Celgene's I&I franchise. From April 2013 to March 2016, Curran served as the U.S. Commercial Head of the I&I franchise.

6. On April 1, 2017, Smith became President and Chief Operating Officer ("COO") of Celgene. At that time, Defendant Curran, who was the President of Worldwide Markets I&I, became the President of I&I and the Chairwoman of the IIEC.

7. Betty Jean Swartz ("Swartz") was a Vice President of U.S. Market Access at Celgene from April 2016 to January 2018.

8. Robert Tessarolo ("Tessarolo") served as a Vice President and General Manager of I&I at Celgene from September 2015 to April 2017.

9. On March 21, 2014, Celgene announced that Otezla, a drug Celgene developed and commercialized as part of its I&I franchise, was the first oral therapy approved by the U.S. Food and Drug Administration (the "FDA") for the treatment of adults with active psoriatic arthritis ("PsA").

10. On September 23, 2014, the FDA approved Otezla for the treatment of moderate to severe plaque psoriasis ("PsO").

11. Psoriasis is an immune-meditated disease (a disease with an unclear cause that is characterized by inflammation caused by dysfunction of the immune system) that causes inflammation in the body and occurs because the overactive immune system speeds up skin cell growth. The National Psoriasis Foundation estimates that psoriasis affects more than 8 million people in the U.S. and 125 million people worldwide.

12. Psoriatic arthritis is a chronic, inflammatory disease of the joints and where tendons and ligaments connect to bone. For many people, psoriatic arthritis starts about 10 years after psoriasis develops, but some develop PsA first or without ever developing or noticing psoriasis. Psoriatic arthritis affects about 30% of patients with psoriasis.

13. On April 27, 2017, Celgene held a Q1 2017 earnings call which was available publicly by webcast at www.celgene.com. The earnings call was also transcribed.

14. In a press release dated April 27, 2017, and during the April 27, 2017 earnings call, Celgene disclosed that Otezla net sales for Q1 2017 were $242M.

15. During the April 27, 2017 earnings call, Celgene presented a slide deck which was publicly available to investors and analysts on Celgene's website.

16. During the April 27, 2017 earnings call, Carter Gould ("Gould"), an analyst with UBS, asked the following question:

> Good morning, guys. Thanks for taking a question. On OTEZLA, it definitely sounds like you're positioning the performance, the seasonal and sort of temporary and I guess, very much in line with what we heard from Amgen last night in the broader segment. Can you just walk through what gives you confidence growth will bounce back or could we see continued pressure in the near term? Thank you.

In response to Gould's question, Curran stated:

> Thank you, Carter. Yeah, I think you're spot on. I think there was really three key drivers to the performance in the first quarter. Firstly, we saw contraction in the market as we saw increased GTN as a result of the contracting, but importantly, that really gives us access to double the number of insured lives going forward. And lastly, we saw minimal drawdown of the inventory.

> Importantly, if we look at the underlying dynamics to the business, they're exceptionally strong. If you look at the market share, OTEZLA continues to grow market share. We continue to gain more than 40% of new patients and these new contracts will give us access to an additional pool of patients moving forward. Importantly, if we look at the exit run rates out of quarter one and into quarter two, we do see the net sales rebounding and on track to deliver the 2017 guidance.

17. On July 27, 2017, Celgene held a Q2 2017 earnings call, which was available publicly by webcast at www.celgene.com. The earnings call was also transcribed.

18. In a public press release dated July 27, 2017, and during the Q2 2017 earnings call, Celgene disclosed that Q2 2017 Otezla net sales were $358 million.

19. During the July 27, 2017 earnings call, Celgene presented a slide deck which was publicly available to investors and analysts on Celgene's website.

20. During the July 27, 2017 earnings call, Curran stated as follows, among other statements:

> Q2 was an outstanding quarter for Celgene I&I, highlighted by significant sequential growth for OTEZLA. Key OTEZLA performance indicators continue to strengthen, and market share and prescriber adoption increased significantly in both U.S. and internationally.
>
> We announced positive results from RADIANCE, our second Phase III trial for ozanimod in MS, and are on track to file the U.S. NDA by year end. We are very pleased with the progress of the program and look forward to the data being presented in an upcoming major medical meeting. Additionally, progress continues for GED-0301 and other important pipeline programs.
>
> Global OTEZLA net sales in Q2 was $358 million, which represents growth of 49% year on year and 48% versus Q1, revenue being driven by continued gains in treatment adoption, geographic expansion and improved market access. With reimbursement now secured across key European markets in Japan, uptake is accelerating rapidly. Ex-U.S. sales have more than doubled versus last year. In addition, we have advanced multiple future growth drivers for OTEZLA, namely initiating enrollment of the Phase III scalp psoriasis trial and completion of enrollment for both the Phase II study in ulcerative colitis, and Phase III trial in Behçet's disease. As a result of continued strong commercial execution, we anticipate continued revenue growth through the second half of the year and expect full year revenue to be in the lower half of the guidance range.

> In the U.S., OTEZLA experienced a rebound in revenue underpinned by strong brand fundamentals. We saw an increase in script volume and continue to command a significant leadership position for new-to-brand share in both psoriasis and psoriatic arthritis. Additionally, while it's early, we are pleased to see accelerating growth in the plans we have contracted with to remove biologic step edits.
>
> In 2 markets where OTEZLA was recently launched, France and Japan, uptake is already exceeding competitive benchmarks. In France, we achieved a differentiated access position that enables physicians to prescribe both within and beyond the hospital setting, resulting in OTEZLA surpassing all recent launch analogues in the category. In Japan, unlike biologics, OTEZLA can be prescribed by community dermatologists, which is fundamentally disrupting the treatment paradigm. In just 3 months since launch, OTEZLA has gained 38% of new-to-brand switch patients in this setting.

21. The closing price of Celgene's common stock on October 25, 2017 was $119.56 per share, and the closing price of Celgene's common stock on October 26, 2017 was $99.99 per share.

22. Multiple sclerosis ("MS") disrupts the normal functioning of the brain, optic nerves, and spinal cord through inflammation and tissue loss, causing communication problems between the patient's brain and the rest of the body. MS is the most common autoimmune disease of the central nervous system, affecting an estimated one million people in the U.S. Most people with MS have relapsing MS ("RMS"), which is characterized by a relapsing-remitting disease course, whereby a patient's symptoms may remit for a period of time but then relapse.

23. The drug Ozanimod was initially developed by Receptos, Inc. ("Receptos"), a San Diego, California-based biopharmaceutical company, to treat RMS and Ulcerative Colitis.

24. In July 2015, Celgene entered into an agreement and plan of merger with Receptos, pursuant to which Celgene would acquire Receptos and its drug, Ozanimod, which was in Phase III clinical trials for the treatment of RMS, for $7.2 billion through a series of merger transactions. In August 2015, Celgene closed its acquisition of Receptos, which resulted in Receptos becoming a wholly-owned subsidiary of Celgene. Ozanimod was incorporated into Celgene I&I.

25. Beginning in 2016 and until March 2018, Martin was Celgene's Corporate Vice President and the Managing Director of Celgene-Receptos in San Diego.

26. Dr. Jay Backstrom ("Backstrom") was the Chief Medical Officer ("CMO") at Celgene from 2016 through 2018.

27. Matthew Lamb ("Lamb") was Celgene's Vice President and Global Head of Regulatory Affairs in I&I from April 2015 to November 2019.

28. Jean Louis Saillot, M.D. ("Saillot"), served as Vice President of Project Leadership, Regulatory Affairs, and Clinical Pharmacology at Receptos from November 2016 to November 2019.

29. Jonathan Tran ("Tran") served as the Executive Director of Clinical Pharmacology at Receptos from July 2015 through November 2019.

30. Susan Meier-Davis, Ph.D. ("Meier-Davis") was the Senior Director in Pre-Clinical Sciences at Receptos from April 2016 to 2018.

31. David Kao ("Kao") served as the Senior Director of Regulatory Affairs at Receptos from July 2015 to April 2016 and then as the Executive Director of Regulatory Affairs at Receptos from May 2016 through April 2020.

32. Gerlee Thomas ("Thomas") was the Director of Regulatory Affairs at Receptos from July 2016 to March 2018.

33. A new drug application ("NDA") is the application through which drug sponsors formally propose that the FDA approve a pharmaceutical for sale and marketing in the U.S. for one or more specified medical conditions.

34. In October 2016, Celgene commenced a radiolabeled mass balance study for Ozanimod.

35. On June 22, 2017, through the mass balance study, Celgene confirmed RP-112273 as a new Ozanimod metabolite.

36. On October 28, 2017, at the MSParis2017-7th Joint American-European Committee for Treatment and Research in Multiple Sclerosis ("ECTRIMS"), Martin stated, "So the RADIANCE studies -- the RADIANCE study and the SUNBEAM study will form the basis of our submission to the FDA and to EMA [European Medicines Agency]. For the FDA, we are working hard as we speak to get ready to file by the end of the year and early next year for EMA."

37. On January 8, 2018, Celgene issued a press release that stated, among other things, that Celgene expected an "FDA decision on the submission of an NDA for ozanimod in patients with relapsing multiple sclerosis (RMS)."

38. On January 25, 2018, Celgene filed a Form 8-K with the United States Securities and Exchange Commission, which stated, among other things, that an NDA "was submitted with the FDA for ozanimod in relapsing multiple sclerosis (RMS) based on data from the phase III RADIANCE™ Part B and SUNBEAM™ trials evaluating ozanimod in patients with RMS."

39. On February 7, 2018, Celgene filed a Form 10-K with the United States Securities and Exchange Commission, which stated, among other things, that:

> Differentiated oral therapies are advancing through mid- to late-stage trials in inflammatory diseases, including ozanimod, a potential best-in-class S1P receptor modulator. In December, a New Drug Application (NDA) was submitted with the FDA for ozanimod in RMS based on data from the phase III trials evaluating ozanimod in patients with RMS. In addition, ozanimod has a phase III trial in UC underway and a phase III trial in CD that is initiating.

40. On February 26, 2018, Celgene received a Refusal to File letter ("RTF") from the FDA concerning the Ozanimod NDA.

41. On February 27, 2018, Celgene issued a press release, which stated:

> Celgene Corporation (NASDAQ:CELG) today announced that it has received a Refusal to File letter from the United States Food and Drug Administration (FDA)

> regarding its New Drug Application (NDA) for ozanimod in development for the treatment of patients with relapsing forms of multiple sclerosis. Ozanimod is a novel, oral, selective sphingosine 1-phosphate 1 (S1PR1) and 5 (S1PR5) receptor modulator. Upon its preliminary review, the FDA determined that the nonclinical and clinical pharmacology sections in the NDA were insufficient to permit a complete review. Celgene intends to seek immediate guidance, including requesting a Type A meeting with the FDA, to ascertain what additional information will be required to resubmit the NDA. "We remain confident in ozanimod's clinical profile demonstrated in the pivotal program in relapsing forms of multiple sclerosis," said Jay Backstrom, M.D., Chief Medical Officer and Head of Global Regulatory Affairs for Celgene. "We will work with the FDA to expeditiously address all outstanding items and bring this important medicine to patients."

42. The closing price of Celgene's common stock on February 27, 2018 was $95.78 per share, and the closing price of Celgene's common stock on February 28, 2018 was $87.12 per share.

43. On April 25, 2018, Celgene disclosed the Metabolite.

44. On April 29, 2018, Morgan Stanley issued an analyst report entitled "More Bread Crumbs Yield Less Confidence In Ozanimod."

45. On March 25, 2019, Celgene resubmitted the Ozanimod NDA to FDA (the "rNDA").

46. On May 24, 2019, the FDA filed the rNDA.

IV. PLAINTIFF'S CONTESTED FACTS (State separately for each plaintiff. Proofs shall be limited at trial to the matters set forth below. Failure to set forth any matter shall be deemed a waiver thereof).

A. Plaintiff intends to provide the following contested facts with regard to liability:[1]

1. The Class Period is the period from April 27, 2017 through April 27, 2018, inclusive.

2. Court-appointed Lead Plaintiff and Class Representative AMF asserts claims on behalf of itself and a class of investors who purchased or otherwise acquired the publicly traded common stock of Celgene during the Class Period, and held those shares through at least one of the three alleged corrective disclosure dates (October 26, 2017, February 27, 2018 and April 29, 2018) in this case (the "Class").

3. The market for Celgene common stock was efficient throughout the Class Period.

4. As a U.S.-listed public company, Celgene released earnings and other corporate information on a quarterly basis during the Class Period. The Company did so through public filings on SEC Forms 10-Q and 10-K, and also through quarterly earnings calls, press releases, and investor slide presentations Celgene posted publicly on its website in conjunction with its quarterly earnings calls. The Company also published publicly available press releases upon important corporate events at other times throughout the year.

5. The alleged misstatements and omissions in this case, including Defendant Curran's statements on April 27, 2027 and July 27, 2017, Defendant Martin's statements on

[1] These Contested Facts incorporate by reference the contents of Plaintiff's other submissions that form part of the Pretrial Order, including, without limitation, Plaintiff's deposition designations and exhibits, and Plaintiff's expert reports. The non-inclusion of any facts in this section is not a waiver of Plaintiff's rights to raise any such facts at trial.

October 28, 2017, and Defendant Celgene's statements on October 26, 2017, January 8, 2018, January 25, 2018 and February 7, 2018, were public.

6. The alleged misstatements and omissions in this case, including Defendant Curran's statements on April 27, 2027 and July 27, 2017, Defendant Martin's statements on October 28, 2017, and Defendant Celgene's statements on October 26, 2017, January 8, 2018, January 25, 2018 and February 7, 2018, were material.

7. The alleged misstatements and omissions in this case, including Defendant Curran's statements on April 27, 2027 and July 27, 2017, Defendant Martin's statements on October 28, 2017, and Defendant Celgene's statements on October 26, 2017, January 8, 2018, January 25, 2018 and February 7, 2018, were made in connection with the purchase or sale of Celgene securities.

8. In connection with the acts alleged by Plaintiffs, Defendants directly or indirectly used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and facilities of the national securities markets.

9. The alleged corrective disclosures in this case occurred on October 26, 2017, February 27, 2018 and April 29, 2018.

10. The Class includes Class members who purchased Celgene common stock between the dates of Defendant Curran's alleged misstatements and omissions on April 27, 2027 and July 27, 2017 and held those shares through the alleged corrective disclosure on October 26, 2017.

11. The Class includes Class members who purchased Celgene common stock between the dates of Defendant Celgene's alleged misstatements and omissions on October 26, 2017, January 8, 2018, January 25, 2018 and February 7, 2018 and held those shares through the alleged corrective disclosure on February 27, 2018.

12. The Class includes Class members who purchased Celgene common stock between the dates of Defendant Celgene's alleged misstatements and omissions on October 26, 2017, January 8, 2018, January 25, 2018 and February 7, 2018 and held those shares through the alleged corrective disclosure on April 29, 2018.

13. The Class includes Class members who purchased Celgene common stock between the date of Defendant Martin's alleged misstatements and omissions on October 28, 2017 and held those shares through the alleged corrective disclosure on February 27, 2018

14. The Class includes Class members who purchased Celgene common stock between the date of Defendant Martin's alleged misstatements and omissions on October 28, 2017 and held those shares through the alleged corrective disclosure on April 29, 2018.

15. As the President of I&I, Defendant Curran actively participated in Celgene's process for preparing and making public disclosures to the market regarding financial performance and clinical development matters in the I&I franchise. Curran directly reported to Scott Smith

16. Curran was responsible for providing, reviewing, and/or approving language in Celgene's earnings call scripts, investor slide decks, press releases, and SEC Forms 10-Q and 10-K that discussed clinical development matters within the I&I franchise and the financial performance of I&I products.

17. Curran served on Celgene's IIEC, and she became its Chairperson after her promotion to I&I President. The IIEC, which was comprised of senior members of the I&I franchise, made strategic decisions and oversaw I&I's business operations. Membership included representatives from each of the functional departments – legal, finance, commercial, regulatory, development, and compliance. Curran also attended Celgene's Executive Business Review

("EBR") meetings, during which the leaders of each Celgene franchise reviewed performance and operational trends, including the latest forecast estimate for Celgene products such as Otezla.

18. In his role as President of Celgene I&I, Scott Smith oversaw the clinical development, global registration, and commercial sales of drugs within the I&I franchise.

19. During the Class Period, Defendant Martin was Celgene's Vice President of Leadership & Project Management – Immunology and Managing Director of Celgene-Receptos in San Diego. Martin was a member of the IIEC. From January 2014 to June 2016, Philippe Martin ("Martin") served as Celgene's Vice President of Project Leadership & Project Management for Immunology.

20. Martin reported directly to Smith until April 1, 2017, and then reported directly to Curran from April 1, 2017 until the end of the Class Period.

21. Martin provided updates regarding the Ozanimod NDA to the IIEC at meetings of the IIEC, among other means.

22. Smith generally relied on information he received about Ozanimod from Martin and Curran as well as FDA guidance.

23. Celgene's most successful drug was Revlimid, a blockbuster chemotherapy drug that accounted for over $8 billion in Celgene's global sales and over 60% of the Company's total revenue in 2017. After the launch of Revlimid in 2006, the drug quickly became a blockbuster for Celgene. By 2010, Revlimid accounted for $2.4 billion in annual product sales—roughly 70.4% of Celgene's total annual net product sales—and, by the end of 2014, Revlimid accounted for $4.9 billion in sales. For five consecutive years prior to the Class Period, Revlimid had delivered over half of the net product sales for the entire Company. In 2014, net product sales from Revlimid accounted for $4.98 billion, or more than 65% of total net sales for the Company as a whole.

24. On January 12, 2015, Celgene announced its five-year strategic growth plan. Celgene stated that its I&I franchise was "expected to exceed" $3 billion in net sales by 2020—and Otezla net sales in 2017 would range between $1.5 and $2 billion.

25. During the Class Period, Celgene faced the looming expiration of Revlimid's patent protection, which was set to expire in 2022. In December 2015, Celgene agreed to provide Natco Pharma Ltd. with, among other things, a volume-limited license to sell a generic version of Revlimid in the U.S. commencing in March 2022. Celgene executives knew that the "lions' share" of Celgene's business was at risk once Revlimid came off patent protection.

26. Thus, Celgene required a new drug pipeline to offset the anticipated loss in revenue from the entry of generic alternatives to Revlimid in the marketplace.

Otezla

1. Celgene Depended on Otezla to Replace Anticipated Future Revenue Losses, But the Drug Was Beset by Poor Efficacy and Product Adoption and Experienced Flattening Market Performance Trends Prior to the Adoption of Otezla's 2017 Budget

27. One of the drugs that Celgene depended upon to replace the Company's revenue stream from Revlimid was Otezla (apremilast). Celgene touted Otezla as being among its "multiple potential blockbuster products in I&I" and as a drug that was expected to lead the Company towards "significant growth through 2020 and beyond."

28. Otezla is a small molecule drug approved as a treatment for adult patients with moderate to severe PsO and PsA.

29. The FDA first approved Otezla in March 2014 for treatment of PsA, followed by its approval in September 2014 for treatment of PsO.

30. The overall PsO and PsA markets included other drug-based treatments, such as topicals applied to the skin, phototherapy used for PsO only, NSAIDs, DMARDs, and biologics.

Biologics are different from traditional systemic drugs that impact the entire immune system. Biologics only target specific parts of the immune system.

31. Formularies define which medications will be covered, under what circumstances, and at what cost to the patient, and distinguish between preferred and non-preferred products by dividing medications into "tiers," each with a different level of patient cost sharing. For drugs in higher tiers, patients typically pay either a higher fixed amount (copay) or a higher percentage of the cost of the drug (coinsurance). If a drug is not included in the formulary, then patients are typically responsible for the full cost of the drug unless a specific exception is granted.

32. If a drug has a prior authorization requirement, a health care provider typically must obtain approval from a health insurance plan that the drug is medically necessary before the patient can receive a prescription.

33. In some instances, plan sponsors and pharmacy benefit managers ("PBMs") require step therapy. Step therapy or "step-edits" are a common cost-control strategy that require patients to try a lower cost prescription drug that treats a given condition before stepping-up to a similar acting, but more expensive drug.

34. By mid-2016, Otezla faced numerous challenges in increasing sales and market share, and Celgene executives, including Curran, received multiple pieces of negative information about Otezla's efficacy and product adoption, the overall PsO and PsA markets, and Otezla's decelerating market share.

35. For example, in 2016, even though over 99% of commercially insured patients had coverage for Otezla, 67% of these patients were required to unsuccessfully try at least one biologic product before their insurance company would offer coverage for Otezla. For example, in 2016, Aetna required PsA patients to first try and fail with either methotrexate or at least two NSAIDs

and then try and fail with at least two separate biologics with preferred formulary status (such as Enbrel and Humira) before Aetna would offer insurance coverage for Otezla. Other major payers like Anthem, Express Scripts ("ESI"), and Humana had similar step edit restrictions in place for Otezla.

36. Further, by as early as August 2016, Celgene executives knew that Otezla's market share growth had stalled, that its new prescription trends were flattening, and that its new-to-brand capture was leveling out. Curran acknowledged that she knew by October 2016, during the initial preparation of the 2017 Otezla Budget, that Otezla's market share was moving "at a slower pace."

37. Actual market data supported these negative trends. By the second half of 2016—before Celgene set its 2017 Budget—Celgene executives including Curran knew that Otezla's market share within the PsA and PsO markets had already begun decelerating, as Otezla was reaching full product adoption.

38. Otezla's PsA market share began stagnating early in 2016, and, by August 2016, Otezla's PsA market share within a broader, more representative market basket had been flattening for over a year. Similarly, Otezla's PsO market share began decelerating throughout 2016, slowing to a rate of less than a tenth of a percent per month. The significant deceleration in Otezla's market share reflected that the product was reaching maturation.

39. Other information available to Celgene executives, including Curran, in 2016 supported these negative data points about Otezla. Celgene-commissioned surveys (such as "Wave" surveys produced for Celgene by Naxion) and other public reports (such as those conducted by the UK's National Institute for Health Care and Excellence ("NICE"), industry market intelligence firm Datamarket, the Canadian Drug Expert Committee ("CDEC"), and the Institute for Clinical and Economic Review ("ICER")), were critical of Otezla's efficacy in

comparison to competing treatments. In fact, certain reports ranked Otezla at the bottom of all possible drugs for the treatment of PsO and PsA and found that the proportion of patients "quitting due to lack of efficacy is on the rise." One report explicitly noted that this lack of efficacy was "a critical factor in suppressing [Otezla's] share growth." For example, a December 2, 2016 report authored by ICER found that Otezla had "the lowest relative effectiveness" across all possible PsO treatment outcomes.

40. These reports were consistent with the overall assessment of Otezla by the pharmaceutical industry and practicing physicians. Otezla was viewed by the industry as a niche treatment for 5-10% of patients who were "needle shy" or who had "contradictions to [methotrexate] and biologics." Plaintiff's expert, Dr. Simon Helfgott, a rheumatologist at one of the largest clinical practices in the United States (Brigham and Women's Hospital) and an Associate Professor of Medicine at Harvard Medical School, opined that, "Otezla was inferior to [] other treatments due to its well-documented inferior efficacy compared to biologic drugs, and higher cost compared to conventional systemic treatments with similar efficacy, such as methotrexate, another oral therapy." Celgene's expert, Dr. Gary Solomon, acknowledged that Otezla was a product appropriate for only a "selected subset of patients" and "select groups of patients." According to Dr. Solomon, "Otezla is less powerful than many of the biologic agents" for the treatment of PsO and PsA, and methotrexate was effective as Otezla. In fact, Solomon personally prescribed Otezla only to approximately 5% of his patients.

41. The market's perception of Otezla's poor efficacy represented a challenge to gain greater market access with insurance payers, particularly given the availability of other systemic treatments like methotrexate (the most popular, and a less expensive therapeutic) and biologics

(the most effective therapeutics). One confidential third-party report issued to Celgene by Naxion concluded that Otezla had reached "market stasis" in 2016.

42. Likewise, physicians reported that Otezla patients suffered nausea and gastrointestinal side effects, particularly diarrhea, which outweighed the perceived benefits of its use. Factors such as relative efficacy, tolerability, patient adherence, and cost are important considerations for practitioners in selecting a systemic treatment for PsO or PsA. Otezla's inferior efficacy, poor tolerability, and inferior patient adherence made Otezla a poor treatment choice for the majority of patients, leading many to discontinue treatment. Celgene executives recognized that these negative prescribers' views were relevant in setting Otezla's budget and forecast estimates.

43. Further, additional competitors entered the marketplace in 2016 with treatments directed at the same indications as Otezla, with more competitors scheduled to enter the marketplace in 2017. Heading into 2017, Otezla thus faced numerous entrenched competitors with a higher percentage of market revenue (Humira, Enbrel, and Stelara), as well as new products that would experience a higher rate of growth.

2. Celgene Entered Into Managed Care Contracts That Were Not Expected to Drive Any Revenue Growth in 2017 and That Presented a Risk That Otezla Would Not Meet Budget Expectations Absent Driving Significantly More Demand and Market Share to Non-Contracted Plans

44. Celgene executives attributed stalling sales and market growth in part to restrictions imposed by insurance payers at the point of sale. These "bio-step edits" prevented U.S. patients from gaining access to Otezla without first being required to fail at least one biologic competitor product and/or methotrexate.

45. In an attempt to overcome this serious barrier, and expand Otezla's use as a pre-biologic treatment, Celgene sought the removal of biologic step-edit restrictions to allow Otezla

to attract patients who had been moving directly from no treatment or a first-line treatment to a biologic. Specifically, Celgene entered into managed care contracts with three large payers, ESI, Prime Therapeutics ("Prime"), and Aetna, which ensured Otezla a bio-step free formulary position with those pharmacy benefit managers ("PBMs") as of January 1, 2017.

46. However, the price that Celgene paid to enter into these agreements included rebates, price protection on Revlimid, and a steep discount on Otezla sales. Further, the methotrexate step edit remained in place, meaning that patients would have to first use methotrexate before Otezla even under the managed care contracts.

47. Celgene executed the new managed care contracts at or around the same time that the Company was finalizing its 2017 Budget in fall 2016.

48. Internally, Celgene determined that its Otezla contracting strategy (which offset Otezla price increases due to discounts) was not expected to yield any net revenue growth for Otezla in 2017, but rather would have a negative net sales impact for the year.

49. As the managed care contracts were not expected to generate any net revenue in 2017, Otezla's discounting strategy required "significantly more" demand in the non-contracted plans. To reach even this "impact neutral" status based on the new managed care contracts, Celgene executives realized that "[f]ailing to deliver on an inflection in market share would risk performing to our currently submitted 2017 budget."

50. Given decelerating market shares and the expected negative net revenue impact of the managed care contracts in 2017, Otezla's forecasted net revenue growth could only be driven by increased unit sales (and market share) outside of the managed care contracts and outside of planned net price changes.

51. In general, unit sales expand when (i) the overall market expands and/or (ii) a product increases its share of the market. In setting the 2017 Otezla Budget, Celgene assumed that both would occur; thus, failing to do so would result in Celgene missing the budget. The 2017 Otezla Budget assumed that the overall PsO and PsA markets would expand by 13% and 8%, respectively. In addition, the 2017 Otezla Budget assumed that Otezla's market share within the PsO and PsA markets would increase by 17.2% and 9.1%, respectively. The 2017 Otezla Budget forecast 671,000 units and U.S. net revenue of $1.309 billion, premised on these assumptions, which included the execution of the Company's managed care contracting strategy.

52. Yet, Otezla faced challenging prospects outside the managed care business. Otezla lacked contracts with two of the largest PBMs—CVS Health (Caremark) and Optum Rx (United Healthcare)—which imposed significant step-edits and other restrictions, making it difficult for patients to obtain Otezla through those plans. These two PBMs, which accounted for nearly half of PBM-managed prescription claims in 2017, would have been an unlikely source of growth for Otezla in 2017 without contracts in place to increase product access. It was thus unlikely that Otezla would experience any growth from within these plans, which covered a large pool of potential patients.

53. In addition, non-U.S. Otezla sales, which comprised approximately 14% of the low-end of the public guidance and budget, were characterized internally at Celgene as a "super stretch target" and could not offset any shortfalls in the U.S. budget.

3. Certain Celgene Executives Recognized That Otezla's 2017 Budget Was Unattainable, Which They Communicated to Defendant Curran on Multiple Occasions

54. Celgene executives recognized that Otezla's 2017 growth targets were unattainable from their inception. In fact, as set forth below, Curran was explicitly warned in multiple IIEC

meetings between the third quarter of 2016 and the first quarter 2017 that Celgene was at risk of meeting its budgeted forecast for Otezla net sales.

55. For example, as early as September 2016, Robert Tessarolo, the general manager of the United States I&I market, who reported to Defendant Curran, notified Curran that even "neutral" sales required "significantly more demand" in managed care contracts, and that without an inflection point in market share, Celgene risked missing the 2017 Budget.

56. Tessarolo also warned Curran and members of the IIEC on multiple occasions in the fall of 2016 through the first quarter of 2017 that the 2017 Otezla net sales forecast was at risk because, due to the impact to net sales from the payer contracts, Otezla was going to fall short of the forecast.

57. Former Otezla executive Betty Jean Swartz ("Swartz"), Celgene's Vice President of Market Access, who reported to Tessarolo, testified that she was "personally in meetings" in which Tessarolo "warned the IIEC [I&I Executive Committee] that the 2017 net sales guidance was at risk and needed to be lowered," and that "he said it more than once." Swartz testified further that the potential lowering of the Otezla guidance was "a pretty prevalent topic" during that time: "These were conversations that came up fairly often" with Curran and other senior Celgene executives. Swartz testified that despite Tessarolo's suggestion that Celgene had to lower its Otezla forecast because Celgene was going to fall "very short" of the benchmark, Curran and Scott Smith (Celgene's President and Chief Operating Officer) pushed back and said that they would not change the forecast guidance.

58. Swartz testified that she believed as of late 2016 that the 2017 Otezla Budget "was just not achievable." Swartz reached this conclusion "based on the factors of the other competitors coming into the marketplace, based on the payer contracts[.]"

59. Likewise, former Celgene executive James Kilgallon, Celgene's Executive Director of Pricing and Contracting, testified that Celgene submitted a 2017 budget plan with "very aggressive market growth" and that Company executives realized shortly thereafter "that market growth may not continue because Otezla had... already pulled a number of patients off the sidelines to treating within the class and that phenomenon may not continue." Kilgallon testified that he was present in an IIEC meeting and recalled that Tessarolo directly conveyed the risk identified "that we [Otezla] were not going to meet our numbers." Kilgallon further testified that Tessarolo told him and Swartz about a separate "meeting just with Terrie" in which Tessarolo presented the risk directly to Curran. According to Kilgallon, the warnings from Tessarolo were "not well-received" by senior Celgene executives, including Curran.

60. Contemporaneous documentary evidence confirms Kilgallon's account. As Kilgallon wrote in a September 2016 internal email, Tessarolo tried to convey to Curran and other IIEC members "that 2017 will suck" for Otezla because there would be "pain" in 2017 as a price for market access. Kilgallon further testified that Hunter Smith, the Vice President of Finance for the I&I Franchise, who reported to Curran and was a member of the IIEC, had concerns about the financial impact of the rebate levels for the ESI, Prime, and Aetna contracts, that the timing assumption of market share gains posed a risk to the Otezla forecast, and that if the Company did not hit the market share gains it would pose a "downside risk to the financials that we were presenting."

61. Tessarolo ultimately resigned from Celgene in mid-March 2017, before the end of the first quarter of 2017.

4. Despite Knowledge of Significant Risks, Celgene Set an Aggressive 2017 Budget for Otezla Based on Performance Indicators That Underperformed

62. In January 2017, Celgene finalized the 2017 U.S. Budget for Otezla, ultimately setting its internal Otezla global budget for 2017 at $1.57 billion. For the U.S., Celgene projected sales of 671,000 Otezla units, gross revenue of $1.940B, a "GTN Rate" of 32.6% and net revenue of $1.309B in 2017. Celgene also projected quarterly Otezla unit sales for 2017 as follows: 141,776 units in Q1, 160,082 units in Q2, 176,189 units in Q3, and 193,052 units in Q4.

63. The budget provided that Celgene could only meet its Otezla forecasts if: (i) the market expanded and Otezla's market share grew considerably; and (ii) Otezla unit sales increased independent of Celgene's efforts to improve market access through new managed care contracts. The budget also included a $70 million "risk adjustment" to account for potential risks from managed care contracts. Once set, the budget did not change.

64. Plaintiff's expert, Dr. Chris Stomberg, who will testify at trial about industry forecasting practices and Otezla's forecasting practices, opined that "Celgene did not adhere to well-accepted pharmaceutical industry performance assessment and forecasting principles when it projected 45% net revenue growth in its 2017 Otezla Budget," as "[m]arket fundamentals did not support the growth targets set by Celgene for Otezla in 2017." As Dr. Stomberg has further opined based on the evidence:

> Celgene did not follow reasonable industry practices in forming its 2017 Otezla Budget. It based the Otezla US budget on market share growth assumptions that ignored important contemporaneous evidence that those assumptions were highly unrealistic. Instead, Celgene appears to have justified its assumptions on the basis of market analogues that were no longer relevant (and may never have been) now that Otezla had been on the market for two years and was facing real competition. Celgene then seems to have deviated from these unreliable market share assumptions in its 2017 Budget by adjusting them further upward. Real world data clearly communicated a different reality: Otezla was maturing, and its market share growth was rapidly decelerating as it faced strong competition. The 2017 Otezla Budget was unreasonable and unreliable.

65. Celgene based its public guidance on its budget and interim forecast estimates. On January 9, 2017, Celgene issued a press release announcing that it was updating the sales guidance for Otezla, and that it expected Otezla net sales of "approximately $1.5 [billion] to $1.7 [billion]" for 2017, reflecting a 57% "year-over-year change" based on the mid-point of the guidance range. This guidance was at the low-end of the 2017 Budget.

66. Celgene thereafter produced updated forecasts on a quarterly basis, which the Company measured against the budget and the public guidance. These intra-year updates were referred to as the "latest estimate," or LE. The forecasting methodologies and models used to prepare the budget and the LEs were essentially "the same." I&I executives were "owners of their numbers," and their performance expectations were tied to hitting the forecast and budget.

67. As Hunter Smith testified, Celgene reviewed its public guidance on a quarterly basis "at the highest levels of the [C]ompany," including whether the guidance would be "increased, decreased,... narrowed or widened" based on the quarterly forecast.

68. Multiple Celgene internal documents identify the primary metrics upon which Celgene evaluated Otezla's performance and constructed its forecast, including:

a. Market share;

b. Market access exit shares of the contracted plans (ESI, Prime, and Aetna);

c. Market growth;

d. Unit sales;

e. Net revenue attainment versus budget;

f. Total and new prescription growth;

g. Inventory trends; and

h. New patient growth.

69. Terrie Curran herself identified as Otezla's "key metrics" the following: Otezla's monthly and YTD net sales vs. budget; PsO/PsA market share vs. competition and the Company's internal goal; Otezla's new-to-brand share; Otezla "prescriber breadth and depth," and "inventory DOH."

70. The metrics identified above are also those used by professionals across the pharmaceuticals industry to measure product performance. Dr. Stomberg identified numerous key performance indicators used by pharmaceutical companies to track product performance and uptake, as well as to forecast sales trajectories—including total prescriptions (TRx), new prescriptions (NRx), new-to-brand prescriptions (NBRx), market share, market size and growth, syndicated surveys and prescribing trends, daily/weekly sales figures, inventory days on hand (DOH), gross-to-net (GTN) information, and historic calendarization data. Defendants' expert, Dr. Brian Reisetter, identified similar "product performance metrics" tracked across the industry, including "unit sales, gross revenue, net revenue, market shares, as well as pharmaceutical data from third party vendors, such as IQVIA (formerly known as IMS) and Symphony Health," which he has "relied on" as part of his "strategic assessment" of pharmaceutical companies.

71. Douglas Bressette, Senior Director, Global Business Planning and Analysis for I&I, who was one of the primary Celgene executives responsible for Otezla forecasting, testified that the "available data that was relevant to the Otezla forecasting model" included "TRx and NRx data published by third-party prescription healthcare data firms, IMS, and Symphony," as well as "market shares of Celgene's product relative to... other products sold for that same disease area" and information about market volume. Bressette also testified that the level of product inventory is relevant to the budget and the forecast, and that "prescribers' views of Otezla relative to competing therapies" were relevant to "assessing some of the assumptions that go into the

forecast." Likewise, Hunter Smith confirmed that Celgene quantified the revenue risk of Otezla failing to satisfy specific metrics, such as market share, market growth, and market access.

5. Multiple Key Otezla Performance Metrics Underperformed in the First Quarter Of 2017, as Otezla Missed Its Forecasting Targets By Tens of Millions of Dollars

72. By the first quarter of 2017, none of the necessary conditions to meet the 2017 Otezla budget had occurred. The market had not expanded, Otezla's market share had not grown, and Otezla's unit sales had not increased independent of new managed care contracts.

73. In early 2017, Otezla's actual sales underperformed Celgene's unrealistic budget and public guidance targets. The net sales shortfall began almost immediately within the first quarter of 2017, as Celgene entered 2017 with a large inventory overhang exiting 2016 due to wholesalers stocking additional Otezla in advance of a scheduled year-beginning price increase.

74. Celgene executives recognized that the lack of January 2017 sales was "exacerbated by robust inventory levels," as "[i]nventory levels may prolong sales slowdown even as demand returns to growth." In response to an expected price increase, Otezla wholesalers had already accumulated enough inventory to have product for approximately 20 days on hand ("DOH"), which was well in excess of normal ranges of 10-13 DOH. As Douglas Bressette testified, the "inventory stocking was a surprise" that directly impacted the budget and forecast, and, had Celgene executives "known that distributors wanted to hold 20-plus days on hand, we would have had the opportunity to factor that into our Q1 [forecast]."

75. It took a self-described "significant" draw down in inventory to decrease Otezla's inventory to a normalized level of DOH by quarter end. In particular, Otezla's DOH metric fell from 20 DOH at the end of 2016, to 17 DOH in January 2017, to 12 DOH in March 2017. Curran noted in internal presentations that "Significant inventory drawdown through the first six weeks of 2017 drive soft year-to-date performance." Curran also confirmed that she recalled discussing

the "significant inventory drawdown" during the first quarter of 2017. Later in the quarter, Celgene attributed "inventory adjustment" as one of the key factors "driving Q1 weakness."

76. Yet, even beyond the "inventory adjustment," Celgene experienced problems with lower demand for Otezla early in the first quarter of 2017, with I&I executives noting in January 2017 that "we are lagging big time" and that "we are long past digestion of the December buy-in so the issue is demand." That is, specialty pharmacies were not purchasing Otezla from wholesalers at the level (and price point) that Celgene had forecasted. Executives acknowledged that "[i]nventories have contracted considerably since January while demand also slumped," leading to a reduction of the gross sales forecast of $73 million and a reduction of $34 million in net sales. These executives explicitly rejected the theory that inventory adjustment was the sole reason for the Otezla sales slump.

77. By early-February 2017, Curran knew Otezla sales were significantly underperforming the 2017 Budget. Curran regularly reviewed how sales were tracking against the budget and forecast, and she knew that Otezla's actual revenue was at only 55% of the budget as of early February. Curran also had access to Celgene's Daily Sales Report, which showed in the first quarter of 2017 that Otezla sales were at variance with (and below) the budget and forecasts.

78. By the end of February 2017, Celgene had adjusted the 2017 Otezla global budget downward by $70 million. Internal Celgene documents indicated that multiple sales metrics were underperforming and that Otezla's sales drop in January 2017 was unprecedented in terms of size and scope. An email from Tessarolo to Curran dated February 21, 2017 included a slide titled "Latest Thinking Summary," which reduced the total number of forecasted Otezla unit sales for the first quarter of 2017 from 141,776 to 117,300 units, creating a 24,500-unit variance to the 2017 Budget.

79. Celgene knew that the underperformance was material to investors. In mid-February 2017, after receiving an email that Otezla sales trends were "very soft" and required sales increases of "100% above the levels we have seen until now," CFO Peter Kellogg responded (in an email that went to Celgene's CEO Mark Alles) that it was "important to note that the Street is well ahead of this Budget/forecast for Otezla, so that will be the main issue for Q1, even if we get back to Budget." He remarked further that "we should plan our verbal commentary, and whether there should be some pre-emptive signaling during the Quarter to get the street better aligned."

80. By February 24, 2017, Curran's "latest thinking" was that Otezla would miss the first quarter 2017 Budget by at least $34 million.

81. Celgene's Corporate Finance Group created a Weekly Sales Analysis Report to provide a view of expected sales based on the historical trend of daily sales patterns. As of early-February 2017, the Corporate Finance Group recognized that sales were "significantly below where we would expect," and that "a very significant uptick" of a "73% increase on the average daily sales to date [was] needed to achieve the Budget." The Corporate Finance Group also questioned the I&I franchise's inability to provide updated and accurate forecast numbers. In late February 2017, Celgene Senior Vice President of Global Finance Jürg Oehen chastised the I&I franchise, stating, "[W]e need more regular automatic updates from I&I and one source of the truth." He thereafter remarked to Celgene CFO Kellogg, "The updated forecast seems very ambitious and I have serious doubts on whether we will get there."

82. Otezla's underperformance in the first quarter of 2017 was related in large measure to its inability to grow market share, as well as the failure of the overall PsO and PsA markets to grow according to Celgene's expectations.

83. Multiple internal Celgene documents received by Curran and other Celgene executives revealed that Otezla's market share within the PsO and PsA segments was flat to decreasing in the first quarter of 2017. Curran recognized that the Company's Board of Directors could view the existence or perception of a "flat" Otezla market share negatively, writing in response to a Q1 presentation: "Just met re Q1 and Bod messaging...Feedback re BOD deck – ***don't like market share as it looks flat...***"

84. Internal Celgene documents received by Curran and other Celgene executives also revealed that "Market Growth Appears to be Cooling – PsA and PsO" and that "Volumes Show Consistent Weakness in Q1." On March 10, 2017, Curran commented as to one of these presentations: "Interesting. As I look more closely, ***market growth does seem to be cooling in both segments***." During her deposition, Curran stated that the term "both segments" referred to the PsA and PsO market segments, and that she was commenting about the current market basket of products.

85. By March 8, 2017, Celgene reduced the latest internal estimate for U.S. Otezla sales by $40.5 million relative to the U.S. Budget. Celgene also downgraded its internal unit sales forecast for the first and second quarters of 2017 by approximately 25,000 units and 12,000 units, respectively.

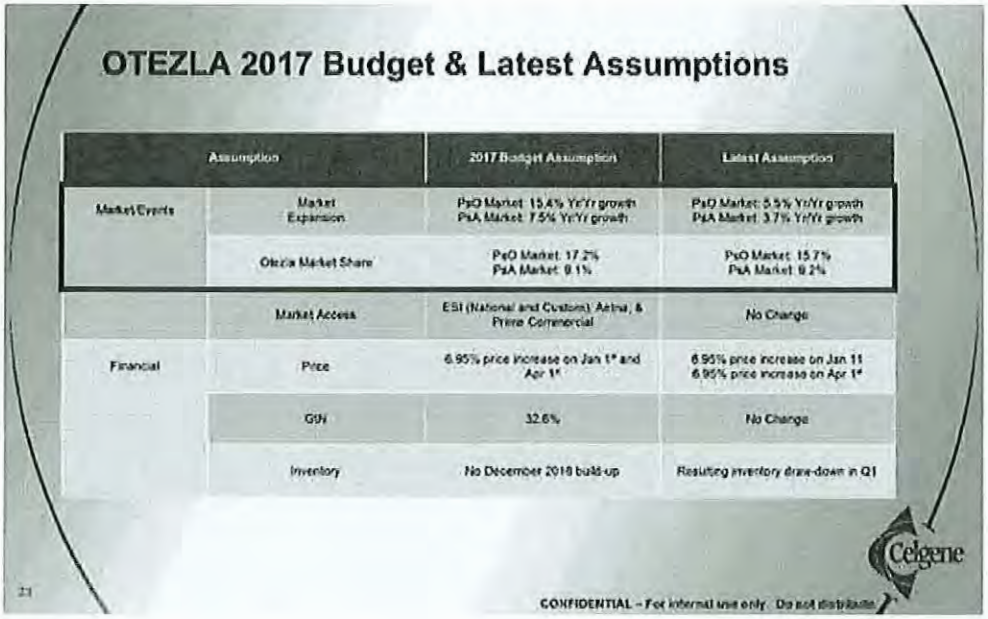
86. Despite an awareness that Otezla sales would not meet first and second quarter estimated sales, Curran and members of Celgene's I&I finance team inexplicably assumed that, for the second-half of 2017, Celgene would sell thousands of sales units more than previously forecasted (approximately 25,000 units). These unexplained additions—unconnected to any underlying data about actual or expected growth—were made outside the normal forecasting process, contrary to industry practices, and only after meeting with Curran. In order to satisfy that

updated, irregular forecast, Otezla would have required a further price increase on top of the increase already contemplated in the budget (from 6.95% to 9.95%).

87. As of March 20, 2017, Otezla global net sales were only at 80% of the 2017 Budget on a quarter-to-date and year-to-date basis. Otezla U.S. net sales were only at approximately 76% quarter-to-date and year-to-date of the U.S. Budget. In just one month, between February and March 2017, Otezla's net sales miss for the first quarter increased by an additional approximately $18 million.

88. Additional negative performance indicators impacted Otezla's ability to meet its Budget and public guidance. For example, a March 2017 slide deck listed several "Variance Drivers," including (i) "Demand: Market growth has slowed down"; (ii) "Inventory build-up in Q4 2016 affected shipments in Q1"; and (iii) "GTN impacted as lower demand has primarily affected lower discounted volumes," i.e., sales outside of the managed care plans that Celgene depended upon to meet the budget. Further, Otezla's international sales were lagging 18% behind the 2017 Budget for the first quarter of 2017. By March 23, 2017, Bressette recognized that Celgene was "never going to hit" the Budget without a price increase, which was never implemented.

89. Given underperforming market growth and market share, as reflected in a presentation prepared for Curran dated March 24, 2017, Celgene correspondingly downgraded its internal budget assumptions:



OTEZLA 2017 Budget & Latest Assumptions

Assumption		2017 Budget Assumption	Latest Assumption
Market Events	Market Expansion	PsO Market: 15.4% Yr/Yr growth PsA Market: 7.5% Yr/Yr growth	PsO Market: 5.5% Yr/Yr growth PsA Market: 3.7% Yr/Yr growth
	Otezla Market Share	PsO Market: 17.2% PsA Market: 9.1%	PsO Market: 15.7% PsA Market: 8.2%
	Market Access	ESI (National and Custom), Aetna, & Prime Commercial	No Change
Financial	Price	6.95% price increase on Jan 1st and Apr 1st	6.95% price increase on Jan 1 6.95% price increase on Apr 1st
	GtN	32.6%	No Change
	Inventory	No December 2016 build-up	Resulting inventory draw-down in Q1

Celgene

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90. The Presentation, which was marked "For internal use only" and "Do not distribute," assumed a much lower growth rate in the PsO market (only 5.5%, compared to 15.45% in the budget) and the PsA market (only 3.7%, compared to 7.5% in the budget). And it assumed that Otezla's PsO market share would decrease by approximately 1.5% from the assumption built into the 2017 Budget. Altogether, the 9.9% contraction in the PsO market growth rate, the 3.8% contraction in the PsA market growth rate, and the 1.5% reduction in Otezla's expected PsO market share reflected an approximately $140 million risk to the 2017 Budget and the Company's public guidance based on I&I's self-established "Opportunities and Risks" assessment.

91. The "Budget & Latest Assumptions" slide further recognized that Celgene erred in assuming "No December 2016 build-up" in inventory, as the latest assumption was a "Resulting inventory draw-down in Q1." Since the market share and market growth assumptions were vital to generate the unit growth needed to achieve the 2017 Otezla Budget, these changes would likely have a dramatic impact on Celgene's sales projections for 2017—especially for the PsO market opportunity.

92. Crucially, Otezla's managed care plans within each of the critical PBMs – Aetna, ESI, and Prime – tracked lower than budgeted. In the first quarter of 2017, TRx volume for each of the three PBMs underperformed the forecasted amount built into the 2017 Budget; and ESI and Prime each underperformed Otezla's within-plan forecasted market share comprised of an eight-drug market basket.

93. Following a March 27, 2017 EBR meeting, Celgene set the March 2017 LE for Otezla at $201 million for U.S. net revenue, a reduction of approximately $55 million from the first quarter of 2017 Budget; and at $43 million for Rest of World ("ROW") net revenue, a reduction of approximately $7 million from the first quarter of 2017 Budget – for a total reduction of $62 million from the 2017 Global Otezla Budget, or 25%.

94. Ultimately, Otezla sales underperformed the 2017 Budget forecast for the first quarter of 2017 by approximately $51 million. Celgene also experienced a "Q1 shortfall of 27k units vs. Budget."

6. Otezla Sales in April 2017 Did Not Make Up the First Quarter 2017 Forecast Shortfall

95. Otezla sales in April 2017 did not increase at a level to make up the substantial first quarter 2017 shortfall.

96. Celgene executives recognized that the continued underperformance of Otezla sales in April made it likely that: "Otezla is on track to... again miss the forecast." On April 18, 2017, Celgene finance executives acknowledged that it had been "[a]nother challenging Monday for Otezla," that "we are falling further behind every Monday," and that it was "hard to belie[ve] that they will get close to their Q2 forecast." In fact, Otezla's year-to-date sales trend was negative as of April 24, 2017 (the last Weekly Sales Analysis Report before the April 2017 False Statement),

leading the Corporate Finance Group to exclude any analysis of the past 5-weeks in sales in projecting future growth based on the "continued volatility of Otezla sales."

97. An internal Celgene email dated April 20, 2017 (sent to Curran's executive assistant), listing Otezla MTD (month-to-date), QTD (quarter-to-date), and YTD (year-to-date) sales with 1-week, 2-week, and 4-week run rates, further showed that Otezla's April 2017 sales as of April 20, 2017 underperformed both the U.S. budget (88% vs. the budget) and global budget (80% vs. the global budget). The same internal document stated that Otezla's YTD sales were well below the U.S. (80%) and global (84%) budgets to date. Finally, the internal document also showed that Otezla's global and U.S. forecasts would fall well short of the global ($1.554 billion) and U.S. ($1.309 billion) budgets, respectively, at 1-week, 2-week, and 4-week run rates, resulting in a 2017 guidance shortfall of approximately $400-500 million:

	Weekly Net Sales Average			Quarterly FCST at run rate			Annual FCST at run rate		
High Geography	**1 week**	**2 weeks**	**4 weeks**	**1-week**	**2-week**	**4-week**	**1-week**	**2-week**	**4-week**
United States	22,593	20,464	21,832	288,367	266,650	280,601	871,268	794,619	843,856
EMEA	2,376	2,950	2,889	31,912	7,673	7,673	93,221	113,885	111,668
Canada	326	305	310	4,217	3,998	4,054	12,638	11,866	12,062
APAC	327	287	214	4,064	3,652	2,909	12,499	11,045	8,423
Grand Total	**25,623**	**24,006**	**25,244**	**328,560**	**312,067**	**324,702**	**989,627**	**931,416**	**976,009**

98. On April 26, 2017, Curran and other Celgene executives received an internal presentation with Otezla U.S. Performance data showing that Otezla's actual net revenue was only 83% of the 2017 U.S. Budget for the year-to-date.

99. The April 26, 2017 presentation further confirmed that April 2017 Otezla sales were at the level forecast originally for just April 2017 in the 2017 Budget, and that Celgene had not made up any ground from the 27,000-unit sales shortfall in the first quarter of 2017. April 2017 weekly average net sales also were not enough to meet targets for the second quarter of 2017. In addition, Otezla's new prescription (NRx) metric was in a downward trend, negative for the

4-week/4-week period and -2.02% below NRx growth year/year. These data further confirmed that Otezla had reached market stasis and would not see the necessary growth in market share and net sales to meet the aggressive forecast and public guidance.

100. The April 26, 2017 presentation also indicated that the overall market had contracted, with declines of approximately 4% in the PsO market over the 4-week market volume metric and declines of approximately 3% in the PsA market over the 4-week market volume metric.

101. In or around April 26, 2017, IIEC members discussed the negative managed care impact and slowing demand, as well as lowering the forecast in light of the growing net revenue shortfall facing Otezla.

7. Defendant Curran Misled Investors Regarding Otezla's First Quarter 2017 Performance and Celgene's Inability to Meet Otezla's Public Guidance

102. On April 27, 2017, in a press release and during an earnings call, Celgene disclosed Otezla net sales for Q1 2017. The net sales of $242M were 21% less than Otezla net sales for Q4 2016 and $60M less than the Q1 budget.

103. During an April 27, 2017 conference call with investors discussing Celgene's results for the first quarter of 2017, Curran addressed a question from an analyst for UBS asking that the Company "walk through what gives you confidence [that Otezla] growth will bounce back" from disappointing results in the first quarter of 2017. In response, Curran stated:

> I think there was really 3 key drivers to the performance in the first quarter. Firstly, we saw contraction in the market as we saw increased [gross to net] as a result of the contracting. But importantly, that really gives us access to double the number of insured lives going forward. And lastly, we saw a minimal drawdown in inventory. Importantly, if we look at the underlying dynamics of the business, they're exceptionally strong. If you look at the market share, OTEZLA continues to grow market share. We continue to gain more than 40% of new patients. And these new contracts will give us access to an additional pool of patients moving forward. Importantly, if we look at the exit run rates out of quarter 1 and into quarter 2, we do see the net sales rebounding and on track to deliver our 2017 guidance.

104. Curran's remarks about Otezla related to the drug's performance in the first quarter of 2017, included materially misleading representations of current facts, and were not forward-looking. Prior to Curran's remarks, during Celgene's prepared remarks, investors were shown slides that included Otezla market share scaled over a 26-month period, and which purported to show that Otezla market share increased in the first quarter of 2017. But Curran's remarks about the "3 key drivers to the performance it the first quarter" did not relate to the previously-shown slides.

105. At the time of her April 27, 2017 Statement (the "April 2017 False Statement"), Curran knew or had access to the following facts, as discussed above, including:

a. Robert Tessarolo directly warned Curran and other senior Company executives on multiple occasions between fall 2016 and the first quarter of 2017 that Celgene's Otezla forecast was at risk—which was a "pretty prevalent topic at the time" with the I&I franchise.

b. Otezla sales significantly underperformed the 2017 Budget forecast for the first quarter of 2017, missed the first quarter of 2017 unit forecast by 27,000 units, and caused the Company to downgrade its unit forecast by approximately 12,000 units for the second quarter of 2017. Q1 2017 Otezla net sales were approximately $60M less than the Q1 budget.

c. Second quarter Otezla sales in April 2017 prior to the April 2017 False Statement did not "rebound" from the unexpected first quarter of 2017 shortfall. Further, internal Celgene documents demonstrated that Otezla sales would fall well short of the 2017 guidance and latest forecast estimate by hundreds of millions of dollars applying run rates exiting the first quarter of 2017.

d. Otezla's PsO and PsA market share began decelerating in 2016 and was flat-to-declining in the first quarter of 2017 and through April 2017.

e. While Curran referenced increased market access based on new managed care contracts, she omitted that those contracts were not expected to yield any revenue growth in 2017, and that the contracts underperformed Otezla's budget forecast in terms of expected prescription volume and market share.

f. In addition, the overall PsO and PsA markets were flat, underperforming market estimates built into the budget. Celgene recognized internally that declining market growth and market share could alone have a $140 million impact on the 2017 Budget.

g. Otezla's inventory far exceeded "normal" levels exiting the first quarter of 2017, causing a "significant" draw down in inventory and leading "inventory adjustment" to be one of the key factors "driving Q1 weaknesses." At her deposition, Curran could not explain the discrepancy between the "minimal" drawdown of inventory, which she conveyed to investors, and the "substantial" drawdown of inventory that she had identified internally.

h. The level of "inventory stocking was a surprise" in the first quarter of 2017, and the I&I Group "probably would have set... the budget" based on the larger inventory so as to "factor that into our Q1 [forecast]."

i. There was significantly less demand for Otezla than forecast in the 2017 Budget.

j. Third-party commissioned market surveys cited Otezla's lack of efficacy and side effects and concluded that the product had reached "market stasis." Those surveys also demonstrated that prescribers viewed Otezla as less effective than comparable

treatments for PsO and PsA. Other public reports reached similar conclusions, which were consistent with the overall assessment of Otezla by practicing physicians and the pharmaceutical industry.

k. "Celgene did not adhere to well-accepted pharmaceutical industry performance assessment and forecasting principles when it projected 45% net revenue growth in its 2017 Otezla Budget," as "[m]arket fundamentals did not support the growth targets set by Celgene for Otezla in 2017."

l. Otezla experienced a 10.1% decrease in new patient growth on a year-over-year basis from Q1 2016 (15,600 new patients) to Q1 2017 (14,030 new patients).

m. Otezla's underlying business dynamics and its prospects for future growth were not exceptionally strong as of April 27, 2017.

106. Because of these negative factors described above, and Otezla's underlying weak performance metrics, the Company's 2017 sales projection for Otezla was not reasonably attainable as of the April 2017 False Statement. Given Curran's knowledge of these undisclosed negative facts, the April 2017 False Statement was made with actual knowledge of the statement's falsity, and, to the extent necessary, any purported cautionary language that accompanied the April 2017 False Statement was not meaningful.

8. Otezla Continued to Underperform Multiple Key Performance Metrics in the Second Quarter Of 2017 and Once Again Fell Short of the Forecast

107. Otezla continued to underperform in the second quarter of 2017, as sales fell short of the second quarter of 2017 forecast, losing further ground as to the 2017 full year budget and public guidance. As in the first quarter of 2017, Otezla's second quarter 2017 sales were impacted by multiple negative factors that would have been relevant and apparent to an industry participant

in assessing Otezla's performance, including: (i) decelerating to declining growth in the overall PsO and PsA market, (ii) flat or declining Otezla market share, (iii) waning patient growth metrics, (iv) underperforming managed care contracts, and (v) floundering physician survey responses that further indicated market stasis. Overall, Otezla net revenues of approximately $600 million in the first half of 2017 underperformed the first half 2017 Budget by approximately $59 million.

108. The original 2017 Otezla Budget set a second quarter U.S. target of $318.3 million, so the U.S. figure alone fell short of the target in the second quarter of 2017 by $12.3 million. This incrementally added to the previous quarter's budget shortfall. With $505 million of U.S. net revenue by the end of the second quarter, another $804 million in Otezla net sales were required to achieve the 2017 goal set out in the 2017 Otezla Budget, which would require the second half of the year to grow a full 60% relative to the first half. Celgene nevertheless reaffirmed the 2017 net sales guidance for Otezla of $1.5 billion to $1.7 billion.

109. Otezla's market share was also flat-to-declining in the second quarter of 2017, which Curran recognized. On May 22, 2017, Curran presented an "Otezla update" to Celgene executive leadership using a slide deck that included statements such as: "Q2 Otezla market shares relatively flat in both PsO and PsA," and "March and April (MTD) volume indicates market is flat." Additional Otezla performance slides, received by Curran and other Celgene executives as late as July 19, 2017, showed that PsO and PsA market share metrics were flat-to-declining.

110. In addition, all three of the critical PBMs, Aetna, ESI, and Prime, underperformed their internal Celgene forecasts both in terms of total unit sales and Otezla's within-plan market share of an eight-drug market basket.

111. The overall national PsO and PsA markets also remained stagnant, failing to grow as forecast.

112. Celgene also experienced even larger Otezla inventories exiting the second quarter of 2017 than exiting December 2016 (one of the factors "driving Q1 weakness"), building to an abnormally high Otezla inventory of 24 DOH exiting June 2017.

113. By early-July 2017, Celgene downgraded its market share assumption both for payers with whom the Company had managed care contracts (the "deal" accounts), and for payers with whom it did not (the "no-deal" accounts). Data from the first quarter of 2017 showed that market share had "flattened" as to the no-deal accounts, suggesting "there does not seem to be anymore [sic] growth in volume at those accounts." Celgene downgraded the peak market share assumption for the "no-deal" scenario to a flat market share scenario.

114. Similarly, by early-July 2017, applying actual data and results, Celgene downgraded the peak market share assumption for the managed care "deal" scenario from 21% to 16%. The market share misses caused the managed care contracts to underperform by tens of thousands of units.

115. The last daily sales report prior to the July 2017 False Statement, released on July 25, 2017, stated that Otezla sales were performing at only 44% of the latest estimate year to date and only 18% quarter to date. Referencing that data, Corporate Finance executives, including CFO Peter Kellogg and Executive Director of Corporate Financial Planning and Analysis Steven Rosen, recognized that Otezla sales were averaging only $13.9 million per week through the first four weeks of July 2017, and that it would take $32.1 million in weekly sales per quarter end—36% higher than the weekly average in the second quarter of 2017, which missed the forecast—to achieve the third quarter 2017 Otezla forecast. Rosen estimated that the average forecast deficit under three scenarios that he and his team had considered was a third quarter 2017 budget variance of $50.8 million.

116. In an email dated July 26, 2017, Celgene's Executive Vice President of National Sales informed sales personnel that Celgene entered the third quarter of 2017 requiring sales and prescriptions to "dramatically increase" given the "flat lined" prescriptions to date, stating: "The way the forecast is now the third quarter has to grow 17% over Q2 and the 4th qtr 23% over q3."

9. Defendant Curran Misled Investors Regarding Otezla's Performance in the Second Quarter of 2017, Including as to Otezla's Market Share, Prescriber Adoption, Key Performance Indicators, and the Company's Ability to Achieve Its 2017 Public Guidance

117. On July 27, 2017, Celgene published a public press release (exhibited with a Form 8-K filing), disclosing that its "Previous 2017 Guidance" for Otezla was "Unchanged." Later, during Celgene's second quarter 2017 earnings conference call, Curran stated that "Q2 was an outstanding quarter of Celgene I&I, highlighted by significant sequential growth for OTEZLA. Key OTEZLA performance indicators continue to strengthen, and market share and prescriber adoption increased significantly in both U.S. and internationally" (the "July 2017 False Statement"). Curran's remarks about Otezla related to the drug's performance in the second quarter of 2017, included materially misleading representations of current facts, and were not forward-looking.

118. Just two days prior to the July 2017 False Statement, however, Curran herself recognized that Otezla's market share had not "increased significantly" in the second quarter. Specifically, among other things, on July 25, 2017, in the lead-up to the second quarter of 2017 earnings call, Curran asked Douglas Bressette how he would "characterize US performance... [s]ales are up significantly versus previous quarter and YOY with market share flat. Therefore, can I say it is a combination of market growth, price and improved Gtn?" In response, on July 25, 2017, Bressette replied that "Overall Otezla's demand growth v. Q1 on relatively flat market share generally tracked the systemic/biologic market basket growth over the same period." Curran then

wrote to Patrick Flanagan of Celgene Investor Relations that "Overall Otezla's demand growth v. Q1 on relatively flat market share generally tracked the systemic/biologic market basket growth over the same period."

119. The underlying data in the chart that Celgene showed to investors during the Company's second quarter 2017 earnings call indicated that Otezla's market share within the six-drug basket decreased in the second quarter of 2017—just as it had in the first quarter of 2017. On July 24, 2017, Curran's assistant emailed a copy of "Terrie's slides" to Curran in connection with Celgene's upcoming earnings call on July 27, 2017, which "reflect[ed] edits from today's prep session." A graphic in that presentation included a draft slide that was ultimately used during the earnings call. The underlying data for the graphic (which was incorporated into the slide deck itself) demonstrated that Otezla's overall U.S. PsO market share for a six-drug market basket decreased over the second quarter of 2017, from 22.5% as of March 31, 2017, to 21.7% on June 30, 2017. The June 30, 2017 Otezla market share of 21.7% was more than a full percentage point below the December 2016 and January 2017 figures (each 22.8%), and contrary to the assertion that Otezla market share "increased significantly" during the second quarter.

120. Additional Otezla market share data for an eight-drug market basket showed that Otezla's PsO and PsA market share decreased in the second quarter of 2017 (from 12.6% to 12.1% in the PsO indication and from 8.2% to 7.6% in the PsA indication). By all metrics, as Curran well knew, Celgene's market share was "materially below" its "Target" levels.

121. During her deposition, Curran conceded that she described the market share as flat two days prior to her public comments, which was consistent with the July 19, 2017 slides she had received showing that Otezla's PsO and PsA 4-week market share metric declined between March 31, 2017, and June 30, 2017.

122. Patient growth metrics also declined in the second quarter of 2017. Otezla's new patient growth (measured on a four-week rolling average basis) decreased throughout the second quarter by approximately 10.2% from the end of Q1 2017 (14,030 new patients) through the end of Q2 2017 (12,724 patients). That significant decrease was consistent with declining year-over-year growth for new patients, which also declined approximately 10.2% in Q2 2017 compared to Q2 2016 (14,174 new patients in Q2 2016 compared to 12,724 new patients in Q2 2017).

123. In addition, Otezla new prescription growth trends also decreased in the second quarter of 2017 on a four-week rolling average. Another metric, Otezla's NBRx, had peaked for both the PsO and PsA indications in August 2016 and had decreased from that high-point in the first and second quarters of 2017.

124. Additionally, Curran received negative information regarding prescriber views as to Otezla. On May 9, 2017, Curran and other I&I executives received slides regarding an updated Awareness, Trial, and Usage ("ATU") study conducted by a third-party to measure patient and physician satisfaction with Otezla. The study found that "Fewer than half of [dermatologists] are confident that patients will be satisfied with Otezla, putting it well below all other therapies but MTX [methotrexate]." According to that presentation, Otezla ranked the lowest of all its competitors in the same market basket for PsO and PsA. Another third-party market study produced for Celgene in May 2017 concluded: "Efficacy, short-term tolerability, and access have always been Achilles heels for Otezla, and there is no sign that clinical impressions are improving, even while strides are being made to broaden access." The inferiority of Otezla led clinicians "to limit the use of [Otezla] to a very small segment of the psoriasis and psoriatic arthritis population."

125. Curran also received additional information in advance of the July 2017 False Statement showing that Otezla's performance continued to weaken in July 2017, between the end of the second quarter of 2017 and the July 2017 False Statement. For example, on July 19, 2017, Curran received U.S. Otezla performance slides with sales data through July 18, 2017, which showed that Otezla sales data as of July 14, 2017 trailed the budget and latest estimate considerably on a monthly/quarterly (19.2% budget, 21.4% latest estimate) and yearly (74.7% budget, 84.0% latest estimate) basis.

126. The July 19, 2017 slides also reported a negative 10.6% 6-week over 6-week decline in net revenue. Based on a 12-week average run rate (which would have accounted for large Memorial Day and July 4th sales from the prior quarter, which still missed the budgeted forecast), Otezla sales were tracking at only 81.9% of the budget and 84.2% of the latest estimate.

127. Likewise, slides provided to Curran and other Celgene executives on July 21, 2017, in advance of an EBR meeting, projected that net product sales were trending $141 million under the third quarter 2017 forecast alone using actual sales run rates.

128. An internal "Otezla LE Update Q3-Q4 2017," dated July 31, 2017, stated: "All metrics for Otezla show flat growth in the last months." Similarly, an "I&I Leaders" slide deck emailed to Terrie Curran on September 6, 2017, stated that Otezla's market dynamics and performance fell below expectations in the first half of 2017, with risk for the second half of 2017 driven by:

a. Substantially lower market growth vs. previous year

b. Managed care controls restricting utilization in the Derm category

c. Uptake in managed care 'wins' plans lower (and slower) than forecasted

d. Post-TNF source of business is declining and not replaced quickly enough with post-topical.

129. Several days later, on September 11, 2017, Curran emailed Steven Rosen confirming her understanding of specific, negative performance metrics throughout the year to date – including market share, market growth, and the performance of the managed care contracts – each of which was known to her prior to the July 2017 False Statement:

- Overall national market share running flat vs increase forecasted in 2017.
  - PsO MS goal was an increase of 5.5%, assuming 15% market growth
  - PsA MS goal was an increase of 2.6%, assuming 7.5% market growth
- At time of developing 2017 forecast goals, Otezla MS was still showing significant growth
- Factors potentially contributing to flat MS growth in 2017:
  - New entrants in PsO & PsA
  - Market growth slowing more than expected
  - More restrictive controls across all MC plans
  - "Wins" plans having lower & slower uptake than forecasted
- Major non-win plans have shown negative share trends:
  - Not signing 2017 contracts may have led to an overall decline in national market share vs. the current flat share

130. In or around the same time in September 2017, Rosen wrote to Hunter Smith's replacement: "My main concern here is that we can't have parallel numbers—the ones the franchise truly believes versus what they have shared with corporate—or we will never have a realistic view of the full P&L for management. But this is something we can discuss and work on going forward. I think your new role will help move this in the right direction. :)." Rosen meant that "a fundamental principle is that you want to have one version of the truth, so you need to make sure your collection and consolidation processes always lead to a single version of numbers that everyone is looking at and referencing."

131. Given Curran's knowledge of the foregoing undisclosed negative facts, the July 2017 False Statement was made with actual knowledge of the statement's falsity, and, to the extent necessary, any purported cautionary language that accompanied the July 2017 False Statement was not meaningful.

132. On October 19, 2017, Celgene issued a public press release announcing that it was discontinuing Phase III clinical trials for GED-0301, an investigational compound being developed by Celgene's I&I division for the treatment of Crohn's Disease. The press release stated that Celgene decided to stop the trials following an October 2017 recommendation of the Data Monitoring Committee, which assessed overall benefit/risk during a recent interim futility analysis.

10. On October 26, 2017, Celgene Was Forced to Slash Otezla's Public Guidance Due to Depressed Market Share, Decelerating Market Growth, Inventory Issues, And Problems With Its Managed Care Contracts – Conditions That Had Existed Throughout the Year But Had Been Concealed From Investors – Leading to Large Investor Losses

133. On October 26, 2017, Celgene issued a press release reporting Q3 2017 financial results and "[u]pdating 2017 guidance and financial targets for 2020." In the press release, Celgene announced that U.S. Otezla net sales for Q3 2017 were $250M and international net sales were $58M for a total of $308M Otezla net sales, a decrease of more than $100 million from the 2017 Budget.

134. In the press release, Celgene announced in connection with its third quarter 2017 earnings call that it had slashed Otezla's 2017 guidance by more than $250 million – providing updated guidance of $1.25 billion compared to the prior guidance of $1.5 billion to $1.7 billion. Celgene also announced that it was lowering the 2020 revenue guidance for the I&I division, which included Otezla, from over $4B to $2.6B - $2.8B (*i.e.*, Celgene lowered the 2020 revenue guidance by $1.2B - $1.4B).

135. On October 26, 2017, Celgene held a Q3 2017 earnings call, which was publicly available by webcast at www.celgene.com. The earnings call was also transcribed. (SUMF ¶ 85)

136. During the October 26, 2017 earnings call, Curran stated as follows:

Q3 2017 was both a challenging quarter for Celgene I&I as well as one of progress on several fronts. OTEZLA continued to produce double-digit year-on-year growth despite challenging psoriasis and psoriatic arthritis category headwinds. Key OTEZLA performance indicators were stable in an increasingly competitive market, and we remain focused on executing against several life-cycle initiatives that will expand the potential population for OTEZLA worldwide. We made good progress on the I&I pipeline and are very excited about the upcoming data presentation for ozanimod and MS at the ECTRIMS-ACTRIMS joint meeting in Paris later this week. The program remains on track for regulatory submission, beginning with the U.S. by year-end and the EMEA in the first half of 2019. We are focused on advancing enrollment for the Phase III UC study, TOUCHSTONE, and initiating the pivotal program in Crohn's disease. Lastly, we will be reviewing the results from the OTEZLA ulcerative colitis proof-of-concept trial by year-end.

Global OTEZLA net sales for Q3 2017 were $308 million, which represents a 12% year-on-year increase. This revenue growth is being driven by positive U.S. TRx growth despite challenging market dynamics. Additionally, significant international growth is being driven by our success in securing a differentiated access position in key markets.

In the past 2 years, the U.S. market for psoriasis and psoriatic arthritis grew strongly, posting TRx growth rates in the high teens versus previous years. This was fueled by new launches, including OTEZLA, which expanded the total pool of patients on treatment. We assumed that category growth rates would maintain these historical levels in setting our 2017 targets.

However, year-to-date through September, both markets have experienced a significant slowdown in growth as a result of increasingly restrictive PBM formulary control.

While OTEZLA demand continues to outpace the overall market, we are seeing lower-than-expected revenue due to market deceleration, increases in gross-to-net discounts to drive biologic step-free access and inventory fluctuations.

Since launch, OTEZLA rapidly established clear leadership in new-to-brand share, and this continues despite numerous competitive approvals. Consistent with our strategy, we continue to maintain leadership in patients in the treatment-naive setting, while share has been somewhat impacted in patients previously exposed to biologics. We remain committed to executing against our core strategies to further open up biologics step-free access, focus on the moderate, post-topical patient segment, execute impactful DTC efforts and further strengthen position advocacy based on real-world utilization.

Now I'd like to comment on the progress OTEZLA is making in some key markets outside the United States. International revenue grew from $31 million in the third quarter of 2016 to $58 million in the third quarter of 2017, an increase of 87%. We expect ex-U. S. revenue contribution to continue to increase.

> Our launch success in both France and Japan illustrate the importance of differentiated access as a key uptake driver. In France, uptake at 1 year since launch exceeds competitive benchmarks. Unlike biologics, OTEZLA does not require an initial prescription in the hospital setting and can be used in psoriasis after only one systemic failure versus 2 biologics.
>
> In Japan, OTEZLA has captured almost half of new-to-brand share of the total systemic market. Unlike biologics, OTEZLA can be prescribed in the community setting versus hospital only and has the broadest label among systemic treatments, including post topical.
>
> We continue to make solid progress in advancing several life-cycle initiatives to drive further OTEZLA growth. Importantly, we are pleased that the Phase III RELIEF trial evaluating OTEZLA for the treatment of active Behçet's disease met its primary and key secondary end points across multiple measures of disease activity. We are planning global submission beginning in 2018. We believe these data are very compelling, and our goal is to become the first and only product approved globally for the treatment of active Behçet's disease. We project this represents a total market opportunity of at least $100 million in peak revenue.
>
> Several other key plans are also advancing and represent further growth drivers for OTEZLA.

137. Celgene also reported global net sales of only $308 million for the third quarter of 2017, a decrease of more than $100 million from the 2017 Budget.

138. During the earnings call, Curran stated that Celgene missed its budget assumptions due to "lower-than-expected revenue due to market deceleration, increase in gross-to-net discounts to drive biologic step free access and inventory fluctuation." Curran also referenced Otezla's depressed market share, which "has been somewhat impacted in patients previously exposed to biologics." Each of these conditions, however, existed as of the time of the April 27, 2017 and July 27, 2017 False Statements.

139. In response to these disclosures, the price of Celgene common stock declined by $19.57 per share, a 16% decrease from the prior trading day. The cumulative abnormal stock price reaction was $18.72 per share. Analysts reacted negatively to the news, calling the Otezla results, among other things, a "surprise" and a "standout for the wrong reasons with a bad miss."

140. Celgene's competitors publicly refuted that there was a slowdown in the overall psoriasis market in the third quarter of 2017, stating instead that market growth "has actually accelerated a bit" in the biologic segment "because you'll have patients that don't get adequate response on OTEZLA that then move on to a biologic." Instead, Otezla was "no longer gaining traction," and "that group of patients and that growth is no longer in the market."

141. Actual Otezla net revenues for full-year 2017 were $1.279 billion – including approximately $1.058 billion in U.S. Sales – falling approximately $221 million below the 2017 Otezla Budget and Celgene's public guidance.

Ozanimod

1. Prior to the Class Period, Celgene Acquired Receptos and Announced that it Would Submit the Ozanimod NDA by Year-End 2017

142. Another drug that Celgene sought to use to replace the Company's revenue stream from Revlimid was Ozanimod.

143. Ozanimod was initially developed by Receptos, a San Diego, California-based biopharmaceutical company, to treat Relapsing-Remitting Multiple Sclerosis ("RMS") and Ulcerative Colitis ("UC").

144. In July 2015, Celgene entered into an agreement and plan of merger with Receptos, pursuant to which Celgene would acquire Receptos and its drug, Ozanimod, for $7.2 billion through a series of merger transactions. In August 2015, Celgene completed its acquisition of Receptos, which resulted in Receptos becoming a wholly-owned subsidiary of Celgene. Ozanimod was incorporated into Celgene I&I.

145. Following the Receptos acquisition, Celgene immediately projected U.S. Food and Drug Administration ("FDA") approval of Ozanimod by 2018, and forecasted potential Ozanimod sales of up to $6 billion per year. Between 2015 and the start of the Class Period on April 27,

2017, Celgene repeatedly told investors that it would file a New Drug Application ("NDA") seeking FDA approval for Ozanimod by year-end 2017.

a. For example, on February 17, 2017, Celgene issued a press release which announced top-line results from the Phase III Sunbeam Trial for Ozanimod. The press release stated: "We look forward to data from the confirmatory phase III RADIANCE trial in the second quarter as we advance toward planned regulatory submissions by year-end."

b. On April 27, 2017, Celgene filed a Form 10-Q which stated: "We have phase III trials underway for ozanimod in relapsing multiple sclerosis." Celgene also issued a press release stating that "Celgene anticipates filing ozanimod for regulatory approval by year-end based on these data." On April 27, 2017, during Celgene's Q1 2017 earnings call, Smith presented a slide titled "2017 I&I Franchise Outlook." Under a section labeled "Advancing Ozanimod Development Programs in MS and IBD," a sub-bullet stated: "Submit ozanimod U.S. NDA in RMS and accelerate global commercial activities."

c. On July 27, 2017, Celgene issued a Form 8-K that stated that "[a]n NDA submission to the FDA, based on the combined phase III SUNBEAM™ and RADIANCE™ trials for RMS is expected by the end of 2017." On July 27, 2017, during Celgene's Q2 2017 earnings call, Smith stated, "[j]ust to add on to the comments, we feel very, very good about the data that's emerging for ozanimod and looking forward to getting it out." During the same July 27, 2017 earnings call, Smith also presented a slide which stated: "Ozanimod positive top-line data in RMS; Advancing towards FDA filing by YE:17." During Celgene's Q2 2017 earnings call, Curran presented slides stating that Celgene's I&I Franchise would "[f]ile ozanimod U.S. NDA in RMS" by year-end 2017 and was "[p]reparing for regulatory submission to the FDA by YE:17."

146. Investors relied on Celgene's representations regarding the timing of the Ozanimod NDA in valuing Celgene's stock, as reflected in analyst commentary prior to the Class Period.

2. During the Class Period, Martin and Other Senior Celgene Executives Provided Information Regarding the Ozanimod NDA to Curran and Smith

147. Martin received information regarding the status of the Ozanimod NDA from numerous leaders of the Ozanimod NDA project and in turn provided this information to Smith, Curran and other senior Celgene executives.

148. Jean-Louis Saillot, M.D. ("Saillot") was Vice President of Project Leadership, Regulatory Affairs, and Clinical Pharmacology at Receptos and reported directly to Martin.

149. Numerous leaders of the Ozanimod NDA project regularly provided information to Saillot and Martin regarding the Ozanimod NDA, including: Tran, Thomas, Kao, and David Wilson ("Wilson"), Clinical Bioanalytical Lead at Receptos, among others.

150. Martin, Saillot, Tran, Thomas, Kao, and Meier-Davis, among others, attended Receptos Executive Committee meetings.

151. Saillot, Tran, Meier-Davis, Kao, and Thomas attended Ozanimod MS Team meetings. The Ozanimod MS Team was a team of department leads responsible for the completion of the Ozanimod NDA. Beginning in 2016, Saillot led the Ozanimod MS Team. Other members of the Ozanimod MS Team included Meier-Davis, who was the nonclinical development lead, and Tran, who was the clinical development lead.

152. In addition, numerous senior Celgene employees were involved with the Ozanimod NDA and provided information to Martin, Smith and/or Curran about the Ozanimod NDA, including: Jay Backstrom ("Backstrom"), Celgene's Chief Medical Officer, and Matthew Lamb ("Lamb"), Celgene's Vice President and Global Head of Regulatory Affairs for I&I, among others. Florence Houn ("Houn"), Celgene's Vice President of Global Regulatory Science, also provided

information regarding the Ozanimod NDA to Lamb and Backstrom, who in turn provided information to Smith and Curran.

153. In his role as Chief Medical Officer, Backstrom led the regulatory affairs group. Backstrom reported to Mark Alles and Smith. Lamb reported to Backstrom.

154. Beginning in early August 2017, Martin, Saillot, Kao, Backstrom, and Lamb, among others, participated in regular "touch base" calls to discuss the progress of the Ozanimod NDA submission. These meetings were "important" because "there was a lot of work to be done between that time point in August and the subsequent NDA submission."

155. A personnel matrix dated March 9, 2017 identifies individuals involved in drafting, reviewing, and approving portions of the Ozanimod NDA, including: Martin, Lamb, Saillot, Tran, Kao, Thomas, and Meier-Davis, among others.

156. Martin testified that it was "an important aspect of [his] job to make sure that … Celgene was involved in the process in the decision-making process" regarding the Ozanimod NDA. Martin explained that the IIEC's role was to "ensure that the I&I franchise was well managed." Martin's main role on the IIEC "was to make sure that the IIEC members [including Smith and Curran] were aware of what the project teams were doing." Indeed, the IIEC "was a big component of communication to ensure that people are aware of what others are doing and… for us to know what else is going on at Celgene[.]" Saillot confirmed that Martin made presentations to the IIEC and updated the IIEC with respect to the Ozanimod NDA during 2017 as "the voice of the group to the IIEC."

157. Smith admitted that he "relied … on information he received about ozanimod from Philippe Martin."

3. Curran Actively Monitored the Progress of the Ozanimod NDA

158. Curran regularly asked Martin questions regarding the Ozanimod NDA. For example, Martin provided information regarding Ozanimod to Curran in advance of Celgene's April 27, 2017 earnings call, and Martin had conversations with Curran around July 2017 related to the Ozanimod mass balance data as "part of the communication that was required for the organization to know about the metabolite and what we are going to do about it."

159. After learning of the Metabolite (defined below), Curran became directly involved in assessing the risks that the Metabolite posed to the NDA timeline. Curran testified that after learning of the Metabolite in July 2017, she "was trying to... understand the situation and reached out to guys that I thought would have expertise in the area." Curran testified that "there were meetings at both the IIEC, as well as the executive committee" regarding the Metabolite. On July 25, 2017, Curran forwarded Martin's email regarding the Metabolite (discussed below) to Jay Backstrom, Celgene's Chief Medical Officer. Curran testified that Backstrom was "the leader of the regulatory affairs team and... [her] peer on the executive committee," and he was "someone that [she] would have looked to for knowledge" about the Metabolite and its impact on the NDA. Curran also forwarded Martin's email to Matthew Lamb, head of I&I Regulatory Affairs. Curran testified that Lamb was "a regulatory expert" and someone who "sat on the IIEC" and "reported to [her] for a period of time." On July 26, 2017, Lamb flagged for Curran "the potential implications" of the Metabolite discovery on the Ozanimod NDA, including "making sure the tox[icology] program has qualified the major metabolite" and that the "clin[ical] pharm[acology] studies were designed adequately to cover metabolite exposure, etc." Curran testified that based on Lamb's email, she understood that the NDA required both ***clinical*** and ***nonclinical*** assessments of the Metabolite.

160. On August 3, 2017, Backstrom forwarded Curran an agenda for a recurring meeting regarding the Ozanimod NDA, which included a review of "potential risks for the submission." Backstrom stated that "[t]his [meeting] should help with transparency," adding that Lamb "should be integral to the upcoming pre-NDA meeting" (discussed below). Curran responded, "I totally agree." On October 11, 2017, Lamb forwarded Curran an update in which he flagged the importance of "having the opportunity to review the draft pre-NDA meeting package prior to submission." Curran forwarded the message to Smith and Martin, stating: "***We need to get much more visibility on the [Metabolite] data as it emerges***."

161. Martin also circulated the FDA's November 21, 2017 Preliminary Meeting Comments (discussed below) to Curran and other Celgene executives on November 22, 2017. After receiving the Preliminary Meeting Comments, Martin was involved in assessing the risks to the NDA submission and discussing those risks with Celgene's senior management, including Curran.

4. Smith and Curran Participated in Celgene's Quarterly Disclosure Process and Drafted, Reviewed and/or Approved Celgene's Statements Regarding the Ozanimod NDA

162. In his role as COO and President of Celgene, Smith routinely participated in meetings with other members of Celgene's management to review scripts and slides in advance of earnings calls and presentations, and had the opportunity to review and comment on each of Celgene's Forms 10-Q, 10-K, and 8-K after these filings were reviewed by the franchise presidents, including Curran. Each quarter, Smith participated in meetings with other members of Celgene's senior management to discuss relevant topics and "the important things for investors and others to know" in advance of quarterly earnings calls and investor presentations.

163. In connection with his drafting, review and approval of Celgene's public statements regarding Ozanimod during the Class Period, Smith relied on information that he received from Martin, other members of the Ozanimod NDA team, and I&I leadership, including Curran.

164. As the President of I&I and Chairperson of the IIEC, Curran actively participated in Celgene's process for preparing and making public disclosures to the market regarding clinical development matters in the I&I franchise. Curran also attended Celgene's Executive Business Review ("EBR") meetings, during which the leaders of each Celgene franchise reviewed performance and operational trends.

165. At the time of Celgene's corporate statements in October 2017 and in January and February 2018, Curran was responsible for providing and reviewing language in Celgene's earnings call scripts, investor slide decks, press releases and SEC Forms 10-Q and 10-K that discussed clinical development matters within the I&I franchise, including the Ozanimod NDA. As Smith testified, the quarterly disclosure meetings were attended by "the management who was going speak," which included Celgene's "CEO, CFO, COO, president, and then the heads of the franchises," i.e., Curran, and any "clinical development issues were handled by the franchise heads." Confirming Curran's active role in drafting, reviewing, and disseminating Celgene's statements, Curran presented slides discussing the Ozanimod NDA during the July 27, 2017 (Q2 2017) and October 26, 2017 (Q3 2017) earnings calls and spoke about the Ozanimod NDA during the January 25, 2018 (Q4 2017) earnings call.

5. Background on the FDA NDA Process, Drug Metabolism, and Mass Balance Studies

166. The FDA's expectations regarding the content of NDAs are set forth in FDA guidance documents ("FDA Guidance") and Manuals of Policies and Procedures ("MAPPs"). The federal regulations governing NDAs state that the "FDA will maintain guidance documents on the

format and content of NDAs to assist applicants in their preparation." FDA Guidance is "prepared for FDA review staff and applicants/sponsors to provide guidelines to the processing, content, and evaluation/approval of applications and also to the design, production, manufacturing, and testing of regulated products." MAPPs, in turn, are "federal directives and documentation of internal policies and procedures."

167. A drug sponsor that conducts a drug development program in a manner that is inconsistent with FDA Guidance and industry customs and practices creates a significant risk that the FDA will take adverse action on the drug's application.

168. Because major metabolites have the potential to affect how a drug operates in the body, the FDA will consider whether any major metabolites exist and, if so, whether they affect the safety or efficacy of a proposed drug.

169. A human mass balance study—also referred to as an absorption, distribution, metabolism, and excretion ("ADME") study—is a study conducted during the drug development process that is used to identify and quantify the circulating parent drug and metabolites following the ingestion of a drug. Typically, a radioactive atom label is incorporated into the drug (usually carbon-14 or tritium) and then the radiolabeled products are analyzed through a chromatographic process.

170. Mass balance studies are typically conducted prior to the initiation of Phase III clinical trials. It is important for an NDA sponsor to understand the way a drug is metabolized and any toxicology and pharmacology implications of metabolites produced in human trials, as the results of clinical species and human ADME studies will bear on the drug's registration and eventual usage. Therefore, an NDA sponsor should conduct mass balance studies prior to initiating large-scale Phase III trials.

171. The FDA's Guidance on Safety Testing of Drug Metabolites ("MIST Guidance"), issued in 2008, calls for "the identification of differences in drug metabolism between animals used in nonclinical safety assessments and humans as early as possible during the drug development process" and warns that "[t]he discovery of disproportionate drug metabolites"—metabolites formed at disproportionately higher levels in humans—"late in drug development can potentially cause development and marketing delays." Development and marketing delays may be caused by, *inter alia*, safety concerns related to a newly discovered metabolite.

172. Pursuant to the FDA's MIST Guidance, disproportionate metabolites and metabolites "formed at greater than 10 percent of parent drug systemic exposure at steady state" can raise a safety concern and require additional testing, including safety testing, general toxicity studies, genotoxicity studies, embryo-fetal development toxicity studies, and carcinogenicity studies. As Lamb testified, "[i]f the metabolite accounts for greater than 10 percent of the parent, it is deemed a major acting metabolite, which then does require some additional characterization to be done."

173. As provided in FDA Guidance, absent agreement from the FDA, an NDA must be complete at the time of submission by the drug sponsor. Incomplete applications are subject to a "refusal to file" ("RTF") by the FDA.

174. An RTF indicates the FDA's rejection of the NDA based on facial inadequacies identified through a summary review of the NDA's contents.

175. Some review issues may render an NDA incomplete and result in an RTF letter from FDA.

6. NDAs Must Contain Bioanalytical Validation Data or Risk a "Refusal to File"

176. FDA Guidance provides that, in connection with an NDA submission, a drug sponsor must submit full clinical study reports ("CSRs"), including bioanalytical validation reports containing long-term stability ("LTS") data covering all samples that have been tested (or "assayed") for a given analyte.

177. Long term stability ("LTS") refers to the stability of a chemical compound(s) within a sample that is stored under the conditions used in a particular study over a period of time, i.e., from when the sample was first collected to the time the sample is subsequently analyzed.

178. As explained by Plaintiff's FDA regulatory expert, Dr. Nicholas Fleischer, "[c]onsistent with the Bioanalytical Method Validation Guidance, the FDA considers a full clinical study report (including for pharmacokinetic studies) to be one that includes bioanalytical validation reports documenting that LTS has been established for 'all samples' that were analyzed in the study." Lamb testified that the FDA expects that an NDA include full CSRs, which include bioanalytical and validation reports, "includ[ing] stability data."

179. Failure to include bioanalytical validation reports with an NDA is one example of a deficiency that may result in an RTF letter.

180. On March 2, 2017, the FDA advised Celgene that "[f]ull Clinical Study Reports are needed... at the time of the NDA submission." This FDA correspondence was distributed to Martin, Saillot, and Tran, as well as Thomas, Kao, and Meier-Davis.

7. FDA Guidance Requires Sufficient Testing to Assess the Safety Profile of a Metabolite that Constitutes the Majority of Human Exposure

181. As explained by Plaintiff's toxicology and pharmacology expert, Dr. Frederick Guengerich, FDA Guidance concerning the testing of metabolites "establishes standards for the pharmaceutical industry in conducting nonclinical safety assessments." Based on this FDA

Guidance, "it is well-established that pharmaceutical companies must conduct sufficient testing to assess the safety profile of a disproportionate metabolite, and that a pharmaceutical company cannot rely on studies undertaken prior to the discovery of a new, disproportionate metabolite because those studies did not consider the impact of that metabolite."

182. The FDA and pharmaceutical companies evaluate the safety of a drug using an exposure multiple (also known as a safety multiple or margin of safety), which refers to the exposure to a certain substance in animals as compared to the exposure in humans. The exposure multiple is a ratio that is calculated by dividing the animal exposure by the human exposure: animal exposure/human exposure = exposure multiple. An exposure multiple of 1.0 or greater means that animal have been exposed to more of the substance than humans, and gives assurance that if the substance was going to present a safety issue, it would have been observed in animals because they were exposed to more of the substance than humans.

183. FDA Guidance provides that if a metabolite composes the majority of the total drug-related human exposure, the safety multiple achieved in the pivotal toxicology studies should be 1.0 or greater.

184. In order to calculate an exposure multiple for a metabolite, a drug sponsor must determine the actual exposure of the metabolite after administration in both humans and animals. Without such data, a drug sponsor is unable to demonstrate safety multiples greater than 1.0 as required by FDA Guidance. As Dr. Guengerich explains, "nonclinical safety multiples based on estimated nonclinical exposure data" is "insufficient to evaluate toxicokinetic data for purposes of a safety assessment"

8. Celgene Discovered a New, Disproportionate Metabolite Late in the Development Process that Derailed the Company's NDA Timeline

185. In accordance with the FDA's MIST Guidance, as well as industry customs and practice, Celgene should have conducted the Ozanimod mass balance study prior to the initiation of the Phase III clinical studies for Ozanimod.

186. Despite clear regulatory guidance to the contrary, the Ozanimod mass balance study was neither planned nor conducted until October 2016, late in the clinical development process and after the initiation of Phase III clinical trials. As Saillot acknowledged in a "Q&A" document sent to Tran on July 17, 2017, the "human mass balance study" was conducted "very late in the development of ozanimod." Saillot further stated: "Such studies are usually planned before or during Phase 2, so that the metabolic profile is completely understood before full clinical development and finalization of the non-clinical safety package, including carcinogenicity studies when needed. There is clear regulatory guidance on when such studies should be done, which was not followed."

187. When Celgene belatedly initiated the mass balance study in October 2016, it recognized that the work plan required to meet the December 2017 Ozanimod NDA filing commitment was "heavily back-loaded" and put a "[h]uge workload on [the] team with little time for delays/errors."

188. As early as January 2017, based on the preliminary results of the mass balance study, Celgene recognized the likelihood of a new metabolite being identified, potentially impacting the NDA submission. Internal communications and meeting minutes confirm this concern.

189. The MS NDA Submission Dashboard for the week of March 27, 2017, which was distributed to Martin, Saillot, and Kao, among others, confirmed that Celgene viewed the "[p]otential to identify a new metabolite" through the mass balance study as a "key issue[.]"

190. Over the following weeks, the Ozanimod MS Team worked to identify the new metabolite, noting the need for follow-up studies and the possibility that Celgene would need to delay the NDA submission to allow time to complete the necessary studies. In early April, Meier-Davis and Esther Martinborough, Executive Director of Biometrics at Receptos ("Martinborough") were tapped to lead a new team charged with overseeing the Metabolite studies.

191. On April 24, 2017, Martinborough sent a presentation to Martin and Saillot analyzing the mass balance study results that stated: "It appears that this new peak is real.... [W]e are assuming that it is a single peak >10% [of Ozanimod's systemic exposure]." The presentation specifically noted the possibility that Celgene would need to delay the NDA submission until September 2018 in order to perform additional studies of the newly-identified metabolite ("273" or "Metabolite").

192. Internal communications reveal that prior to July 27, 2017, the leaders of the Ozanimod NDA, including Saillot, Tran, Martinborough, and Meier-Davis were all acutely concerned with the Metabolite jeopardizing the NDA timing, noting the "importance and urgency" of conducting additional testing on the Metabolite, which they acknowledged "could have a significant negative impact on the NDA deliverables and timeline." These concerns were communicated directly to Martin.

193. For example, on May 16, 2017, Saillot implored Martin to "[p]lease, please, please reconsider" informing Smith of the Metabolite, stating: "In the best case scenario the December timeframe [for filing the NDA] is extremely optimistic. Anything that slows down the progress

(challenges in identification of the components of the peaks, etc…) will put that timeline in jeopardy."

194. In connection with an Ad Hoc Executive Committee meeting on June 15, 2017, Tran prepared a presentation which was shared with Martin that stated that "RP112273 [the Metabolite] is pharmacologically active and more potent (> 10-fold) than Ozanimod.... RP112273 is likely the major and active moiety accountable for most of ozanimod's efficacy and/or safety." On June 22, 2017, Martinborough stated in an email sent to Saillot, Martin, Tran, Meier-Davis and others that Celgene had "definitively confirmed RP-112273 as the peak in human plasma."

195. Following confirmation of the Metabolite, on July 5, 2017, Kao provided Saillot and Thomas with draft language for Celgene's pre-NDA meeting request to the FDA.

196. The FDA encourages applicants to schedule a "Pre-NDA Meeting" in advance of submitting an NDA, in order to facilitate exchanges of information about the submission. Before submitting the Ozanimod NDA, Celgene requested a pre-NDA meeting with the FDA, which was granted and scheduled for November 27, 2017.

197. In order "to permit FDA to provide the sponsor with the most useful advice on preparing [an NDA]," the FDA requires the sponsor to submit a "briefing book" "at least 1 month in advance of the meeting" containing: "(i) A brief summary of the clinical studies to be submitted in the application. (ii) A proposed format for organizing the submission, including methods for presenting the data. (iii) Information on the status of needed or ongoing pediatric studies. [and] (iv) Any other information for discussion at the meeting."

198. The language proposed by Kao acknowledged that Celgene would not have complete data for the Metabolite at the time of the planned NDA submission:

> **PURPOSE OF MEETING**.... Celgene is also seeking FDA feedback and agreement on our proposed plans for the nonclinical qualification and PK/PD

> characterization of 112273, a recently-identified, active major metabolite of Ozanimod. Specifically, Celgene would like to obtain FDA confirmation that it would be acceptable to provide certain data regarding 112273 during the NDA review period [i.e., after the NDA submission] without delaying the PDUF performance goal date, on the basis that Phase 3 clinical trial data are already available and support the safety and efficacy of Ozanimod in RMS [relapsing multiple sclerosis] patients.

199. On July 17, 2017, a "Q&A" document drafted by Saillot and sent to Martin posed the question: "What is the impact on the [NDA] submission [of the Metabolite discovery]?" The response: "Unaddressed this would lead to a Refusal to File by FDA." The document explained that Celgene's plan was "to negotiate submission of the NDA within the original timeframe, with agreement for additional data to be submitted during the review period." As Saillot acknowledged, there was a substantial possibility that the FDA would reject this approach. The document described a "[b]est case" scenario wherein the FDA would accept the limited Metabolite data that Celgene would have by the time of the NDA submission, but warned of a "[p]ossible scenario" wherein the FDA requests additional data, delaying the NDA submission "by 1-2 Quarters" into early 2018.

200. On July 25, 2017, Martin sent Curran an email, which he forwarded to Smith, stating that the "human mass balance study revealed a new disproportionate metabolite RP112273 (>10% of total drug related exposure) which was not previously detected in preclinical species," noting that the "risk of a new metabolite[] was identified by the team in December 2016." As Martin explained:

> As per FDA guidance on safety testing of metabolites (2016), metabolites present at disproportionately higher levels in humans than in any of the animal test species should be considered for (non-clinical) safety assessment. Human metabolites that can raise a safety concern are those formed at greater than 10 percent of parent drug systemic exposure at steady state. Since RP112273 is the major (>10-fold higher in exposure compare to the parent ozanimod) and pharmacologically active, adequate characterization of Clinical Pharmacology properties of RP112273 is required by regulatory agencies.

201. Martin's email to Curran and Smith cautioned that while "recent feedback" from Celgene's external consultants "indicates that our plan/data should be acceptable to the agency and allow us to keep the submission on schedule," "[a] lot of work remains to be done in a very short period of time in order to keep the submission on schedule." In other words, the viability of the NDA depended on whether the FDA accepted Celgene's proposed strategy for addressing the late-discovery of the Metabolite, i.e., submitting incomplete data at the time of the NDA submission and supplementing the NDA during the review period.

202. Celgene's plan to submit an incomplete NDA was inconsistent with FDA Guidance regarding the issuance of RTFs, which provides that absent agreement from the FDA, an NDA must be complete at the time of submission by the drug sponsor. The Manual of Policies and Procedures, Good Review Practice: Refuse to File issued by the FDA's Center for Drug Evaluation and Research ("CDER") similarly "emphasize[s] CDER's expectation that applications are to be complete at the time of submission and that a piecemeal approach to building a complete application through amendments following initial submission is unacceptable."

203. On July 26 and 27, 2017, an email chain described the Metabolite as "material information shared on a need-to-know basis," stating that it had "the potential for major implications for the [NDA] submission[.]" The email confirmed this material information had already been shared with Martin, Smith, and Curran, among others.

204. Despite the internal recognition that the Metabolite jeopardized Celgene's NDA timeline, on July 27, 2017, Celgene issued a series of statements regarding the Ozanimod Phase III clinical trials and the Ozanimod NDA, none of which disclosed the Metabolite discovery or the risks it posed to the NDA. These corporate statements were made in the Company's 2Q 2017 Form 10-Q, in slides presented during Celgene's 2Q 2017 earnings call and published on the

Company's website, and in a Form 8-K. In these statements, Celgene touted, *inter alia*, the "positive top-line data" in the ongoing Phase III Ozanimod clinical trials, told investors that Celgene was "[p]reparing for regulatory submission to the FDA by YE:17," that the NDA was "advancing towards FDA filing by YE:17," and that Celgene would "[f]ile ozanimod U.S. NDA in RMS" by year-end 2017." Celgene's July 27, 2017 public statements regarding the Ozanimod NDA did not mention the Metabolite or the risks the Metabolite posed to Celgene's NDA timeline or the likelihood of FDA approval. Curran participated in the quarterly disclosure process that led to Celgene issuing the July 27, 2017 statements, including by reviewing drafts of Celgene's 2Q 2017 Form 10-Q and by presenting slides containing these corporate statements during Celgene's 2Q 2017 earnings call.

205. Notwithstanding the fact that Celgene "definitively confirmed RP-112273 as the peak in human plasma" on June 22, 2017, and the fact that the Metabolite was a pharmacologically active metabolite that accounted for 89% of the total exposure, Celgene sponsored an article authored by Tran and other Celgene employees published in the *Journal of Clinical Pharmacology in Drug Development* on August 7, 2017, which discussed Ozanimod's safety profile and identified and described three pharmacologically active Ozanimod metabolites (RP101988, RP101075, and RP101442) but not the Metabolite.

9. Defendants Knew or Recklessly Disregarded that Celgene Would Not Have Complete Clinical Study Data to Support the NDA at the Time of October 2017 Ozanimod Misstatements

206. In addition to concealing the discovery of the Metabolite and the need for additional testing, Celgene knew or recklessly disregarded that the FDA would reject the NDA without complete LTS data for the Metabolite—a necessary component of clinical study reports—which further rendered Celgene's publicly-announced NDA timeline untenable.

207. On June 1, 2017, Tran asked Wilson if Celgene could reuse old plasma samples from previously conducted clinical studies to measure and analyze the Metabolite. Wilson explained that "LTS becomes a real concern" as the FDA "won't consider the data as validated." Wilson advised Tran that Celgene would need between 15 months and 4 years of LTS data to cover the samples from several Phase I and Phase III clinical pharmacology studies—data that Celgene would not have by December 2017 when it planned to submit the NDA.

208. Tran relayed this information at a June 1, 2017 Receptos Executive Team meeting, presenting slides on the "Impact of new peak on Clinical Pharmacology Strategy"—the "new peak" being the Metabolite. The presentation stated, "Primary concern: PK [pharmacokinetic] sample stability. Regulatory agencies will not consider data validated due to lack of long-term stability (LTS) data."

209. On June 15, 2017, Tran warned Martin and the Receptos Executive Committee that "Adequate characterization of RP112273 PK and PD properties are required by regulatory agencies," including "[a]nalytical: Information on the stability of the analyte...." Tran's presentation further emphasized that the test results must be "considered validated by regulatory (i.e., with long-term stability data)," and that "results are not considered validated due to lack of long-term stability data for PK samples at the time of filing [the NDA]."

210. On July 17, 2017, Tran gave a slide presentation to Martin and the Receptos Executive Committee entitled, "Clinical Pharmacology Strategy for RP112273 to support NDA submission and review." This presentation was also sent to Martin. On a slide titled "Summary of available Clinical Pharmacology data for Ozanimod at NAD [sic] submission (Dec 2017) and during NDA review (2018)," Tran informed Martin and the Executive Committee that Celgene

would have "[l]imited PK characterization of RP112273 in RMS patients (with no long-term stability data)" at the time of the NDA submission in December 2017.

211. On July 20, 2017, Martin, Saillot, and Tran, among others, met with Celgene's external consultants Dr. Lawrence Lesko ("Lesko"), Dr. Russell Katz ("Katz"), and Dr. David Jacobson-Kram ("Jacobson-Kram"), ostensibly to discuss its plan to provide the FDA with additional LTS data for the Metabolite during the NDA review period. However, the slide presentation prepared for the July 20, 2017 meeting with these consultants did not contain any information regarding the amount of LTS data for the Metabolite that Celgene planned to include in its NDA submission, the portion of samples from the relevant clinical pharmacology studies that would be covered by this data, or any detail regarding when Celgene planned to submit additional LTS data.

212. Lesko testified that he never told Celgene at the July 20, 2017 meeting that the FDA would accept the Ozanimod NDA without the complete characterization of 273.

213. On August 1, 2017, Wilson sent Tran a presentation that confirmed Celgene needed substantially more long-term stability data—between approximately one and three years of data—that Celgene would not have by December 2017, when it planned to submit the NDA.

214. Ahead of an I&I Regulatory Affairs meeting on August 10, 2017, Saillot circulated a set of slides to Lamb, Kao, and Thomas, including one stating under the heading "Bioanalytical" that Celgene needed to "Develop and validate human plasma method for the analysis of RP112273," and warning that "Incomplete Clinical Pharmacology package can potentially lead to Refusal to File."

215. On September 18, 2017, Wilson sent Tran updated long-term stability calculations for the previously conducted studies of Ozanimod which indicated that Celgene would not have

sufficient LTS data for its NDA if it were to be submitted by the targeted goal of December 2017. Specifically, Wilson reported that Celgene would not have sufficient LTS data for multiple studies until at least August 2018 (Study 1906) or December 2018 (Study 1904), and in many cases not until 2019 or later (Studies 1908, 1905, 1902, 301, 201B, and 201A).

216. Despite Celgene's knowledge that it would not have sufficient LTS data to support the planned December 2017 NDA submission and the recognition by Celgene's senior Regulatory Affairs employees that an "Incomplete Clinical Pharmacology package can potentially lead to Refusal to File," on September 26, 2017 Celgene published a slide presentation on its website claiming that Ozanimod was "[o]n-track for NDA submission by YE:17."

217. In October 2017, Celgene finalized its "Briefing Book," a document that is customarily submitted to the FDA in advance of the scheduled pre-NDA meeting with the goal of reaching agreement with the FDA on the planned course of action for submitting the NDA.

218. On October 19, 2017, Lamb forwarded a copy of the draft Briefing Book to Houn, which contained Celgene's proposal to submit LTS data for the Metabolite to the FDA after submitting the NDA in December 2017. In his email to Houn, Lamb stated: "Personally, I don't feel the package is ready for submission and requires substantial rework." Lamb testified that his reaction to the draft Briefing Book was that Celgene should "wait for the Ozanimod NDA submission until [they]'ve completed the studies and CSRs [he] identified." After reviewing the document, Houn agreed: "I don't see the rationale for the delayed metabolite characterization submission by 4 months with the other late CSR submissions."

219. On October 20, 2017, prior to her review, approval and active participation in issuing Celgene's October 26, 2017 corporate statements, Lamb sent Curran his comments to the Briefing Book. On its face, the Briefing Book acknowledged that Celgene could not complete full

and adequate testing on the Metabolite by December 2017, and so requested the FDA's permission to submit an admittedly incomplete NDA. These facts were hard to miss. In fact, the proposed intervals for the submission of LTS data—"approximately 1, 6, 12, 15, 18, 24, 30, and 36 months" after the NDA—reflect the amount of time needed to ***generate*** the LTS data. As explained by Plaintiff's regulatory expert, Dr. Fleischer, in order for clinical study data to be considered validated by the FDA, a drug sponsor must demonstrate that the substance being analyzed remains stable under the same storage conditions for longer than the period within which the sample is analyzed. In other words, it was ***impossible*** for Celgene to generate the required LTS data any sooner than the timeline proposed in the Briefing Book, hence Celgene's request for permission to provide LTS data on a rolling basis after the submission.

220. The Briefing Book acknowledged that Celgene would not have the required LTS data at the time of the planned NDA submission at year-end 2017 and sought agreement from the FDA that its plan to submit incomplete data would be acceptable. The Briefing Book stated: "Specifically, Celgene would like to obtain FDA agreement that it would be acceptable, given the scope of the information included in the initial NDA, to provide additional clinical pharmacology data regarding RP112273 early in the NDA review period..."

221. The Briefing Book included two questions regarding the acceptability of Celgene's deficient LTS data:

> **Question 4:** Does the Agency agree that the overall proposed clinical pharmacology package, including the additional information planned to be provided early in the NDA review, is acceptable and supports the filing for the registration of ozanimod?
>
> **Question 5:** Does the Agency agree with Celgene's proposed timing for the bioanalytical [LTS] data package for the recently-identified major and active metabolite RP112273?

222. In the Briefing Book, under the heading "Supportive Information for Question 5," Celgene stated that it would not have the required LTS data by the time of the anticipated NDA

submission in December 2017 and proposed to submit the additional required data beginning six months after the December 2017 submission and at regular intervals thereafter, stating:

> "[L]ong-term storage stability (LTS) assessments... is ongoing as required to cover samples from the previously completed clinical studies. A method validation report will be provided following completion of core validation activities.... Validation report addenda will be prepared following completion of LTS assessments at intervals of approximately 1, 6, 12, 15, 18, 24, 30, and 36 months....
>
> Celgene plans to provide bioanalytical data as follows:
>
> In the NDA Submission:... As noted above, the validation report for RP112273... will not include LTS assessments....
>
> By the 120-day safety update:... Addendum to RP112273 plasma assay validation report... to include... some ongoing LTS assessments....
>
> Subsequent updates: Ongoing LTS assessments to cover required analysis....

223. Celgene's Briefing Proposal confirms that the Company knew the LTS data was incomplete and that an exception to the FDA's requirements was necessary in order to submit the NDA in December 2017.

224. Despite these and other similar internal concerns, Celgene submitted the Briefing Book to the FDA on October 27, 2017.

225. Notwithstanding this information, which was known to both Curran and Martin, on October 26, 2017, Celgene touted its "phase III trials underway for ozanimod," told investors that it was "[p]reparing for regulatory submission [of the Ozanimod NDA] to the FDA by year-end," that Celgene would "would "[s]ubmit ozanimod U.S. NDA in RMS by YE:17," and characterized Celgene's "[o]zanimod FDA filing in RMS by YE:17" as an inflection point that would drive growth for Celgene. These corporate statements were made in the Company's 2Q 2017 Form 10-Q, in slides presented during Celgene's 2Q 2017 earnings call and published on the Company's website, and in a Form 8-K. These statements included materially misleading representations of current facts and were not forward-looking. Curran participated in the quarterly disclosure process

that led to Celgene issuing the October 26, 2017 statements, including by reviewing drafts of Celgene's 3Q 2017 Form 10-Q and earnings call presentation, and by presenting slides containing these corporate statements during Celgene's 3Q 2017 earnings call.

226. On October 28, 2017, the day after Celgene submitted its Briefing Book, Martin participated in Celgene's Investor Event at the MSParis2017–7th Joint American-European Committee for the Treatment and Research in Multiple Sclerosis ("ECTRIMS"), during which Martin stated that "[f]or the FDA, we are working hard as we speak to get ready to file [the Ozanimod NDA] by the end of the year." Martin's October 28, 2017 statement included materially misleading representations of current facts and was not forward-looking. At the time of this statement, as discussed above, Martin knew about Celgene's Briefing Book proposal and had received extensive additional information concerning the Metabolite and the Metabolite's impact on the timing of the Ozanimod NDA submission. Martin admitted that he relied on "information he received from the Ozanimod project team, including Jean-Louis Saillot, Jonathan Tran, Esther Martinborough, David Kao, Susan Meier-Davis, and Gerlee Thomas" and that his October 28, 2017 statement "was informed by numerous documents, meetings, correspondence, and discussions relating to Ozanimod throughout 2017." Curran also reviewed drafts of Celgene's October 28, 2017 ECTRMIS presentation.

227. Defendants' October 26 and 28, 2017 public statements regarding the Ozanimod NDA did not mention the Metabolite, Celgene's Briefing Book proposal to the FDA to submit incomplete LTS data, or the risks this proposal posed to Celgene's NDA timeline or the likelihood of FDA approval. Critically, at the time of the October 26 and October 28, 2017 statements, Defendants Curran, Martin and Celgene did not know whether Celgene's proposal to submit LTS data after the NDA submission in December 2017 would be acceptable to the FDA. Given

Curran's and Martin's knowledge of these undisclosed negative facts, Celgene's October 26, 2017 statements and Martin's October 28, 2017 statement were made with actual knowledge that the statements were materially false or misleading when made, and, to the extent necessary, any purported cautionary language that accompanied these statements was not meaningful.

228. Curran also promoted the Ozanimod NDA at other investor events in October 2017, including the ECTRIMS conference. Curran also touted Ozanimod's revenue potential in meetings with analysts. Moreover, Curran knew that analyst estimates of Celgene's pipeline revenue assumed that the NDA would be submitted on schedule.

229. Internal communications confirm that Defendants were motivated to conceal the risks that the incomplete LTS data posed to the Ozanimod NDA in their statements on October 26 and 28, 2017 because Defendants sought to reassure investors following Celgene's announcement on October 19, 2017 that it was scrapping development of GED-0301, its development-stage ulcerative colitis and Crohn's Disease drug, and its dramatic reduction in its Otezla sales guidance on October 26, 2017. These negative developments put additional pressure on Celgene to deliver on Ozanimod given the looming loss of Revlimid revenue. For example, a draft Board note from Celgene's CFO, Peter Kellogg to Celgene's CEO, Mark Alles, on October 24, 2017 stated: "We expect that tomorrow could be a volatile day for the stock. The new Otezla trends/outlook and the revised 2020 Targets will cause some investors to become more concerned about our Horizon 2 profile [2022-2025] and whether we have enough pipeline to offset the LOE [loss of patent exclusivity] events in [Horizon 2]. While providing clarity regarding our 2020 outlook will be very helpful, we will... leverage our ozanimod phase 3 MS data at ECTRIMS this weekend to begin to shift the conversation to our pipeline and growth drivers."

230. Investors were encouraged by Defendants' October 26 and 28, 2017 statements regarding the Ozanimod NDA, particularly in light of Celgene's recent I&I disappointments. For example, an October 30, 2017 *FirstWord Pharma Plus* article stated that "Celgene experienced a frightful October in which its market cap fell by almost a third after [GED-0301's] implosion fueled doubts about Revlimid's longevity, so it will come as some relief that last week's RADIANCE and SUNBEAM results produced no big surprises, especially considering the added importance that ozanimod... lives up to its mega-blockbuster potential." This article and similar reports were sent to Smith, Curran, Martin.

231. Internally, Defendants acknowledged the strong likelihood that the FDA would reject Celgene's piecemeal LTS proposal, as evidenced by the fact that Defendants began planning for the FDA's eventual rejection of the Briefing Book proposal and likely need to delay the submission. On November 20, 2017, Lamb emailed Curran about spending "***$150 million***" on a priority review voucher ("PRV"), which is a mechanism for a new drug applicant to expedite the FDA's review of an NDA, in the event "the FDA makes a strong recommendation that we shouldn't submit the NDA until we have all the information on the metabolite available and we decide to wait until March-April 2018 to submit the NDA." Curran stated that she agreed with Lamb's plan. Curran and Lamb then discussed the issue with Smith and Martin.

232. The fact that Curran actively engaged in this contingency planning demonstrates that Curran knew that the FDA was very likely to say no to the Briefing Book proposal. These conversations assumed the FDA's rejection of the proposal and the likely need to delay the submission. The rationale for this planning included "the possibility the FDA might recommend Celgene wait until March or April of 2018 to submit the NDA." Given Curran's awareness of the underlying facts requiring such contingency planning at the time she made or approved Celgene's

October 2017 Ozanimod statements, these communications prove that Curran knew or recklessly disregarded that the October 2017 statements were materially false or misleading when made.

10. Defendants Knew or Recklessly Disregarded that Celgene Would Not Have Complete Non-Clinical Data to Support the NDA at the Time of the October 2017 Ozanimod Misstatements

233. As early as January 2017, Celgene recognized that "[i]f a significant new metabolite is identified, then we will not have sufficient toxicology [data] to support the [NDA] submission." This is because, as Dr. Guengerich explains, "Celgene needed to establish that it could demonstrate the safety of [the Metabolite] through the previously-completed non-clinical studies such that it did not need to repeat those studies, which would take years and significantly delay the NDA submission." However, "Celgene was unable to demonstrate safety multiples greater than 1.0 for [the Metabolite] in certain of the nonclinical studies" because "there were not adequate exposure levels to evaluate toxicokinetic data for purposes of a safety assessment."

234. Celgene employees working on the Ozanimod NDA repeatedly flagged that the late Metabolite discovery meant that the current non-clinical toxicology data would be insufficient. For example, a March 28, 2017 presentation sent by Zoller to Saillot stated that the "[c]urrent tox data package would not be sufficient if a new metabolite is identified in the [mass balance study]," acknowledging this as a "Potential Risk[] to the Ozanimod Submission." Similarly, an April 24, 2017 presentation sent to Martin and Saillot warned of the possibility that Celgene would need to delay the NDA submission by eight months (to September 2018) in order to perform a non-clinical rat carcinogenicity study.

235. In a July 6, 2017 email to Meier-Davis, among others, Tran stated that Celgene would not have "the actual human exposure [for 273] until end of August/early September." This "actual human exposure" data was needed in order to calculate the non-clinical safety multiples for the animal toxicology studies and determine whether these multiples exceeded the

FDA-mandated threshold of 1.0 or greater required for the NDA. As Dr. Guengerich explains, without the actual human exposure data, Celgene had no way of determining whether the exposure multiples generated with the previously-conducted toxicology studies would be sufficient or whether Celgene would need to re-run these studies.

236. During the July 20, 2017 meeting with some of Celgene's external consultants, Jacobson-Kram flagged the FDA's exposure multiple requirements. In an email to Tran (subsequently forwarded to Saillot, Martinborough, and Meier-Davis), Jacobson-Kram stated: "I did not want to interrupt the discussion but in looking at FDA guidance, there is a new twist." Jacobson-Kram then quoted the portion of the FDA Guidance calling for safety multiples of 1.0 or greater when a metabolite composes the majority of total human exposure, as is the case with 273. Jacobson-Kram told Tran to "[p]lease mention this to the group." Significantly, as discussed below, the FDA would later cite this exact provision from the FDA guidance in the November 21, 2017 Preliminary Meeting Comments in discussing what the FDA required in the NDA submission.

237. Importantly, the slide deck Celgene presented at the July 20, 2017 meeting with its consultants contained only estimated human exposure data for 273. Therefore, the FDA consultants could not render any advice as to whether the exposure multiples generated with the previously-conducted toxicology studies would be sufficient under the FDA's requirements.

238. The July 20, 2017 presentation also failed to inform Celgene's consultants that Celgene intended to rely on estimated (not actual) animal exposure data in the NDA submission, which contravened industry practice. As Dr. Guengerich explains: "[T]he analysis used to estimate these multiples (metabolite: parent ratio) is flawed from an analytical standpoint because [the Metabolite] was not characterized in terms of its identity or its separations from other metabolites.

Given the lack of actual, validated [Metabolite] exposure data for certain of the animal species, any metabolite: parent ratios cannot be deemed accurate or reliable."

239. Finally, the July 20, 2017 slide presentation indicated that the safety multiple for the 6-month mouse carcinogenicity study was 0.8, but failed to disclose that the dose used to generate this multiple exceeded the maximum tolerated dose ("MTD"), thus rendering this data point invalid. As Dr. Guengerich explains, safety multiples are typically calculated using the recommended human therapeutic dose and the No Observed Adverse Effect Level ("NOAEL") dose in animals, which is a dose at which no adverse effects are seen. However, Celgene calculated the exposure multiple for certain studies (including the 6-month mouse carcinogenicity study) using a dose above the MTD—the maximum tolerated dose, which exceeds the NOAEL dose. As Dr. Guengerich explains, "toxicity data obtained with mice treated above the MTD dose should not be used to calculate [a safety multiple]" because "any dose exceeding the MTD has some inherent toxicity." Indeed, in an August 1, 2017 email, Meier-Davis expressly told Jacobson-Kram not to consider the safety multiple from the 6-month mouse carcinogenicity study because the dose used to generate that multiple exceeded the MTD.

240. Jacobson-Kram repeatedly raised the need for sufficient exposure multiple data in subsequent emails to Meier-Davis on August 1 and August 23, 2017. Jacobson-Kram warned Celgene that it may need to "repeat an entire M3 package [of toxicology studies] for [the Metabolite]" as the FDA might consider Ozanimod to be a prodrug—a biologically inactive molecule that is metabolized into an active drug—necessitating additional toxicology studies. As Jacobson-Kram explained on August 23, 2017: "The risk is [the FDA] may consider ozanimod to be a prodrug; that may require that RP112273 be studied at higher exposures."

241. On September 19, 2017, Tran provided Meier-Davis and Martinborough the actual human exposure value data for the Metabolite. This data showed that the actual human exposure of the Metabolite was 155,716 pg*h/mL, more than double Celgene's July 2017 estimate of 75,410 pg*h/mL.

242. The actual human exposure data invalidated any prior input from Celgene's consultants regarding the adequacy of the exposure multiples for the Metabolite in several pre-clinical Ozanimod animal studies. For example, the slide presentation used at the July 20, 2017 meeting represented that, based on the estimated human exposure, the 273 safety multiple for the 2-year rat carcinogenicity study was 1.4, i.e., above the 1.0 safety multiple required by FDA Guidance. However, when calculated with the actual human exposure data, this multiple was reduced to just 0.8—i.e., below the necessary 1.0 threshold. Because the safety multiple for the 2-year rat carcinogenicity study included in the July 20, 2017 slide presentation was unsupported by actual exposure data, any advice rendered by the Celgene's consultants at the time of the July 20, 2017 meeting was premised on incomplete data and thus was unreliable.

243. In the Briefing Book Celgene submitted to the FDA on October 27, 2017, Celgene posed the following question regarding the sufficiency of the non-clinical data for the Metabolite:

> **Question 3:** Does the Agency agree that the proposed nonclinical package, including the evaluation of major metabolites, is adequate to support the filing for the registration of ozanimod?

244. Under the heading "Supportive Information for Question 3," Celgene included a table indicating that: (i) the exposure multiple for 273 in the 2-year rat carcinogenicity study was 0.73; (ii) the exposure for 273 in the rat EFD study was 0.2; and (iii) the exposure multiple for the rabbit EFD study was 0.03. These exposure multiples were all below the 1.0 exposure multiple required by FDA Guidance, and also substantially lower that the multiples presented to Celgene's consultants at the July 20, 2017 meeting, which relied on estimated human exposure data.

Celgene's Briefing Book thus acknowledged that Celgene could not satisfy the required exposure multiple for multiple non-clinical studies, and needed the FDA to agree to an exception in order for Celgene to be able to submit the NDA as planned in December 2017.

245. As Saillot testified, the "FDA's willingness to accept post-marketing commitment for these type of issue [sic] is less than in the past." Celgene's expert consultants agreed. Dr. Jacobson-Kram described Celgene's arguments as "***somewhat unprecedented***," adding that "[u]nfortunately, you are dealing with a very conservative [FDA] division[.]" Dr. James MacDonald ("MacDonald"), another Celgene consultant, similarly described Celgene's Briefing Book proposal as a "***red flag***," and testified that Celgene "***clearly had a problem***" because there was a "***firestorm of concern*** [in] regulatory circles around human specific metabolites" and "differential exposures" were "***a white hot area of focus***."

246. Notwithstanding this information, which was known to or recklessly disregarded by Curran and Martin, on October 26, 2017, Celgene touted its "phase III trials underway for ozanimod," told investors that it was "[p]reparing for regulatory submission [of the Ozanimod NDA] to the FDA by year-end," that Celgene would "would "[s]ubmit ozanimod U.S. NDA in RMS by YE:17," and characterized Celgene's "[o]zanimod FDA filing in RMS by YE:17" as an inflection point that would drive growth for Celgene. On October 28, 2017, the day after Celgene submitted its Briefing Book, Martin stated at the ECTRIMS investor event that "[f]or the FDA, we are working hard as we speak to get ready to file [the Ozanimod NDA] by the end of the year." These statements included materially misleading representations of current facts and were not forward-looking.

247. Both Curran and Martin reviewed a draft of Celgene's Briefing Book before it was submitted to the FDA on October 27, 2017. Curran received a copy of the Briefing Book on

October 20, 2017, prior to her review, approval and active participation in issuing Celgene's October 26, 2017 corporate statements and Martin's October 28, 2017 statement, while Martin received a copy of the Briefing Book prior to his October 28, 2017 statement.

248. Defendants' October 26 and 28, 2017 public statements regarding the Ozanimod NDA did not mention the Metabolite, Celgene's question in the Briefing Book whether "the proposed nonclinical package, including the evaluation of major metabolites, is adequate" in light of the deficient exposure multiple data, or the risks the deficient exposure multiple data posed to Celgene's NDA timeline or the likelihood of FDA approval. Critically, at the time of the October 26 and October 28, 2017 statements, Defendants Curran, Martin and Celgene did not know whether the exposure multiple data provided in the Briefing Book would be acceptable to the FDA. Given Curran's and Martin's knowledge of these undisclosed negative facts, Celgene's October 26, 2017 statements and Martin's October 28, 2017 statement were made with actual knowledge that the statements were materially false or misleading when made, and, to the extent necessary, any purported cautionary language that accompanied these statements was not meaningful.

249. As discussed above, internal communications confirm that Defendants were motivated to conceal the risks the deficient exposure multiple data posed to the Ozanimod NDA in their statements on October 26 and 28, 2017 because they sought to reassure investors following Celgene's announcement on October 19, 2017 that it was scrapping development of GED-0301 and its dramatic reduction in its Otezla sales guidance on October 26, 2017, which put additional pressure on Celgene to deliver on Ozanimod given the looming loss of Revlimid revenue. Market commentary following Defendants' October 26 and 28, 2017 statements demonstrates that

investors were reassured by Defendants' statements touting the Phase III Ozanimod clinical study data and timeline for submission of the Ozanimod NDA.

250. After submitting the Briefing Book, Defendants continued to flag deficiencies regarding the safety testing for the Metabolite. For example, in a "Pre-NDA Mtg Prep" document circulated by Kao to Martin, Saillot, Tran and others on November 9, 2017, the Ozanimod team acknowledged that the exposure multiples were "insufficient" because they were below the 1.0 threshold.

251. In a November 10, 2017 email to Meier-Davis, which was forwarded to Martin, Saillot, and Tran, among others, Jacobson-Kram identified the "issues" he believed the FDA would raise with respect to the Ozanimod NDA submission, describing these issues as "the major push back that you can expect from FDA." Among the issues that Jacobson-Kram identified was that while "RP112273 represents the overwhelming majority of drug related material and is responsible for the overwhelming majority of pharmacological activity," Celgene "has less than the clinical exposure for RP112273" for the "rat carcinogenicity study and the segment 2 reproductive toxicology studies." Jacobson-Kram noted that the FDA was likely to question whether the Metabolite has been "adequately tested in these studies[.]" Jacobson-Kram again referenced the possibility that Ozanimod could be considered a prodrug and the possibility that the FDA would require Celgene to "dose animals with RP112273," i.e., conduct new toxicology studies.

252. Dr. MacDonald similarly alerted Celgene to shortcomings in the non-clinical portions of its NDA submission. On November 13, 2017, Saillot sent MacDonald a "run-down of the ongoing activities" regarding the NDA submission, the Briefing Book, and the draft Toxicology Written Summary for the NDA, seeking MacDonald's input. As Saillot explained, "the team is struggling with the best way to address various exposure multiples... as a lot of the work was done

prior to the identification of the new metabolite." According to Saillot, the "bottomline [sic] … will be whether FDA buys our 'total active structurally similar' approach... and if not and they require more tox work, whether a post marketing commitment will suffice."

253. The "total active structurally similar" (also referred to as "total agonist") approach referred to Celgene's attempt to add up the exposures of multiple compounds, including 273, in order to reach a combined exposure multiple above the FDA-required threshold of 1.0 for the toxicology studies—because the exposure of 273 alone did not satisfy the 1.0 threshold. Celgene had previously floated this concept to Jacobson-Kram on November 8, 2017, who indicated he was "not sure FDA will accept this argument," noting he had "never seen this done before." As Dr. Guengerich explains, this approach "is flawed because there is insufficient evidence that any potential toxicity is related to the agonist properties [meaning binding to and activating a receptor to cause a biological response] of the drug or its metabolites." Therefore, the approach "is insufficient to evaluate toxicokinetic data for purposes of a safety assessment and inconsistent with FDA guidance and industry standards, customs, and practices because the pharmacological activity of a metabolite may be totally irrelevant to toxicity issues."

254. On November 19, 2017, MacDonald replied to Saillot with his comments. MacDonald emphasized that "[a] clear acknowledgement" by Celgene that "[t]he late discovery of RP112273 has had an impact on the non-clinical safety evaluation of ozanimod" and "the resulting deficiencies in the [NDA submission] will enhance the credibility of the submission." With respect to Celgene's claim in the Briefing Book that the non-clinical safety multiples for the Metabolite "are mostly above 1, and approach 1..., which would be consistent with the ICH M3 guidance," MacDonald stated: "This is the kind of argument that is a 'red flag' to me.... The simple

fact is that you have no exposure multiple to this major metabolite and you should simply acknowledge that."

255. As MacDonald explained at his deposition, Celgene's representation to the FDA that the exposure multiples for the Metabolite were adequate was "the sort of argument that [FDA] reviewers respond to and that diminishes the credibility of the argument that the sponsor is trying to make, because the data simply doesn't support the statement." MacDonald further testified: "[T]he data they [i.e., Celgene] have, the tables that they presented for review that are in the NDA show quite clearly that there is no exposure multiple. It's not greater than one to this major metabolite in any of the species frankly... and so you just acknowledge that.... [T]he red flag is that you're not trying to deal directly with the data."

256. Saillot forwarded MacDonald's comments to Martin on November 19, 2017, expressing that he was "very concerned about the approvability of the NDA unless these issues [regarding exposure multiples] are addressed."

257. Another Celgene consultant, Dr. Marcie Wood, also flagged the deficient exposure multiple data. In a November 23, 2017 email that was sent to Martin, Wood stated: "I hope that the [FDA] will not be looking for exposure multiples at NOAELs, otherwise none of the tox studies meet this requirement." As discussed above, Celgene calculated the exposure multiple for certain studies using a dose at or above the MTD—the maximum tolerated dose, which exceeds the NOAEL dose.

258. Consistent with the warnings from MacDonald and Jacobson-Kram about the FDA's potential rejection of Celgene's approach for dealing with the exposure multiple for the Metabolite, Lamb acknowledged on November 21, 2017 that "[i]f FDA does not agree with this [total agonist] approach, RP112273 will not be qualified across all tox studies." In other words,

the FDA's rejection of this approach would mean that the non-clinical Metabolite data would be insufficient.

259. As discussed above, Defendants also acknowledged the strong likelihood that the FDA would reject Celgene's Briefing Book approach, as reflected in internal communications among Curran, Martin and Smith considering the use of a PRV. On November 20, 2017, Saillot responded to Martin, Curran, and Lamb regarding Lamb's PRV proposal, stating that a PRV was not a viable option to address the non-clinical deficiencies in the NDA: "I believe the highest risk is in our non-clinical safety argument (particularly the carcinogenicity). I am not sure how a priority review would best play in that scenario...."

11. The FDA Rejected Celgene's Briefing Book Proposal to Submit Incomplete Data for the Metabolite

260. The FDA responded to Celgene's Briefing Book in the FDA's Preliminary Meeting Comments on November 21, 2017. In the Preliminary Meeting Comments, the FDA cited to its guidance on non-clinical toxicology studies and informed Celgene that it did not agree with Celgene's proposed non-clinical data package. The FDA rejected Celgene's "total agonist" approach to measuring exposure to the Metabolite and stated that the NDA submission needed to include actual data, as opposed to estimates. The FDA also informed Celgene that it needed to demonstrate safety multiples of 1.0 or greater for the Metabolite in non-clinical studies.

261. Specifically, in response to Question 3, which asked, "Does the Agency agree that the proposed nonclinical package, including the evaluation of major metabolites, is adequate to support the filing for the registration of Ozanimod?", the FDA did not agree. The FDA stated:

> You should ensure that all circulating major human metabolites (i.e., ≥ 10% of total circulating drug related material) have been adequately assessed in the nonclinical studies (see ICH M3(R2), January 2010; ICH M3(R2) Q&A, February 2013). Interspecies comparisons should be made based on plasma exposure data for each

> major metabolite, not the sum of exposures for parent compound and active metabolites ("total agonist")
>
> Metabolite RP112273 is stated to account for 89% of total drug-related exposure in humans; therefore you will need to ensure that adequate exposure to RP112273 was achieved in a full battery of nonclinical studies, including chronic toxicity, reproductive and developmental, and carcinogenicity studies, in two species. We note that most of the plasma exposure data in animals for metabolite RP112273 are estimated.... You will need to provide toxicokinetic data to document that RP112273 has been adequately assessed in the nonclinical studies. (See ICH M3(R2), January 2010 and ICH M3(R2) Q&A, February 2013.)
>
> The adequacy of the data will be a matter of review.

262. Significantly, in rejecting Celgene's reliance on estimated Metabolite exposure and total agonist approach, the FDA cited the same FDA Guidance calling for safety multiples of 1.0 or greater when a metabolite composes the majority of total human exposure flagged by Jacobson-Kram at the July 20, 2017 meeting.

263. With respect to the clinical data, the FDA explicitly rejected Celgene's proposal to submit additional LTS data during the review period. The FDA informed Celgene that it needed to submit "a complete clinical pharmacology package" including all LTS data "at the time of the NDA submission." The FDA instructed Celgene that if it intended to use retained plasma samples from the Phase 1 studies, Celgene would need to submit evidence demonstrating the stability of the Metabolite in human plasma.

264. Specifically, in response to Question 4, which asked, "Does the Agency agree that the overall proposed clinical pharmacology package, including the additional information planned to be provided early in the NDA review, is acceptable and support the filing for the registration of Ozanimod?", the FDA explicitly responded: "No. A complete clinical pharmacology package, including all relevant PK [pharmacokinetic] and PD [pharmacodynamics] studies... is required at the time of submission." Consistent with its March 2, 2017 correspondence to Celgene stating that

"[f]ull Clinical Study Reports are needed … at the time of the NDA submission," the FDA stated that "[f]ull [Clinical Study Reports] (including the bioanalytical and validation reports) for [the 1001 Study] and all relevant clinical PK and PD studies are needed at the time of the NDA submission." The "bioanalytical and validation reports" that the FDA referenced in its response to Question 4 included LTS data.

265. In Response to Question 5, which asked, "Does the Agency agree with Celgene's proposed timing for the bioanalytical data package for the recently-identified major and active metabolite RP112273?," the FDA stated: "Include the Validation and Analytical Study Reports for all major active metabolites in the CSRs [clinical study reports] for all relevant PK and PD studies. These reports must be available at the time of the NDA submission.... If you used retained plasma samples to quantify RP112273 in the relevant Phase 1 studies, you will need to provide evidence that demonstrates the stability of RP112273 in human plasma at the time of the NDA submission."

266. The FDA's Preliminary Meeting Comments were reviewed by Martin, Smith, Curran, Lamb, Backstrom, Tran, and Saillot, among others.

267. After Celgene received the Preliminary Meeting Comments, internal concern regarding the Ozanimod NDA data grew even stronger. On November 21, 2017, Tran sent an email to Wilson with the subject "Urgent - FDA response," copying the FDA's response to Question 5. Wilson informed Tran that Celgene would "need between a year to almost 2 years to cover the studies" referenced in the FDA's Preliminary Meeting Comments, and sent Tran a table reflecting the LTS data that Celgene needed for each study.

268. By November 22, 2017—the day after receiving FDA's Preliminary Meeting Comments—Celgene decided to cancel its pre-NDA meeting with FDA, which "surprised" Lamb and which he described as a "significant mistake." As Lamb later stated to Smith and Alles: "It

was critical that we met with [the FDA] to establish the path forward and to get a sense of how much they might be willing to work with us."

269. Following the Preliminary Meeting Comments, Lamb began preparing an internal "tracker" memo addressing the gaps in the NDA and warning of the consequences of submitting incomplete data. On November 27, 2017, Lamb asked for Houn's input on the FDA's Preliminary Meeting Comments to prepare this memo, noting that in his view, the "[f]eedback is clear." Houn responded that she hoped Celgene would "NOT submit without all the info as the risk for RTF is real. FDA has warned us. An RTF letter would state: '… on Nov. 21, 2017, we stated you must submit these data with the NDA...'" Houn recommended that Lamb's tracker memo "chang[e] 'Potential RTF issue' to 'RTF issue'" because "[t]he FDA used 'must submit with the NDA' for the missing info." Houn added that "I know this is a company disappointment but hopefully we don't compound our situation." Houn testified that she also discussed her concerns about the NDA submission with Backstrom.

270. On November 27, 2017, Lamb sent the tracker memo to Curran and Backstrom, among others. The memo warned that the need to include the bioanalytical validation reports for all major metabolites in the PK and PD clinical study reports in the NDA at the time of submission—including LTS data for 273—was a potential "Refusal to File issue."

271. On November 28, 2017, Lamb emailed Backstrom regarding the tracker memo, copying Maria Palmisano ("Palmisano"), Celgene's Corporate Vice President for Clinical Pharmacology, and Gondi Kumar ("Kumar"), Celgene's Corporate Vice President for Nonclinical Development, noting that he prepared it following "a number of discussions with Terrie [Curran]." Lamb flagged that the memo addressed "potential refusal to file concerns" for the Ozanimod NDA. In response, Backstrom stated that he "spoke to Scott [Smith] and informed him of our discussions

and of the effort to do a risk assessment with respect to quality of the application [and] potential RTF issues." On November 28 and November 29, 2017, Kumar and Palmisano sent their comments to the tracker memo to Lamb and Backstrom.

272. Curran sent a copy of the tracker memo to Smith on November 28, 2017, stating: "I met with a small team this morning to review the FDAs feedback and will meet later today with the IIEC. Matt will be putting together a document [ ] to document the status of the submission, and mitigation of outstanding issues. I'll update you in person."

273. In connection with his efforts to assess the risk of an RTF, Lamb emailed Saillot, Backstrom, Tran, and Kao on November 30, 2017, asking for more information about the "gap" in the LTS data. In response, Tran summarized the LTS information Wilson had previously provided him on November 22, 2017, explaining that Celgene needed more than one to two years of LTS data to cover the Phase I clinical studies and stating that this data was "required."

274. Following these discussions, Lamb sent an updated version of the tracker memo to Curran and Backstrom on December 1, 2017 removing the word "potential" before RTF. The tracker memo now flagged the incomplete LTS data as a "refuse to file issue."

275. Celgene's receipt the FDA's Preliminary Meeting Comments regarding the non-clinical data raised similar red flags that were in fact "expected" by Celgene's consultants. On November 22, 2017, Meier-Davis forwarded the FDA's Preliminary Meeting Comments to Jacobson-Kram, and asked: "Could you review and provide your opinion on what studies are at risk and whether we should initiate at risk?" In his November 23, 2017 response, which Meier-Davis forwarded to Martin on November 26, 2017, Jacobson-Kram wrote: "As I pretty much expected, they didn't go for the 'total agonist' concept. The major message appears to be

that they want actual data for metabolites, not estimated levels. So as we expected, the major challenge will be the rat carc study."

276. MacDonald similarly described the FDA's Preliminary Meeting Comments as "expected" and "ominous." On November 29, 2017, Saillot provided MacDonald with the text of the FDA's response to Question 3. MacDonald responded that it was "[a]n expected response from the Agency," adding that [t]he ominous wording I see is that the metabolite will be 'a review issue.'" As MacDonald explained at his deposition, the FDA's use of "review issue" was ominous because "[a] review issue is FDA code word or code phrase for we don't agree with your position, and unless you give us something different, we are not going to accept your argument." Thus, "they [Celgene] were going to have a difficult time convincing the agency with the existing data that they had adequately characterized and complied with regulatory expectations."

277. On November 30, 2017, Saillot sent MacDonald a draft of the Nonclinical Overview section of the NDA filing for his review. MacDonald sent Saillot his comments on December 3, 2017, stating the following in the cover email: "The document seems to suggest that everything is OK and the [compound] and metabolites have been well characterized. The data simply don't support that statement and I think it will elicit a negative response in the mind of at least the [FDA] pharm-tox reviewer." MacDonald specifically took issue with Celgene's suggestion that the Metabolite had been adequately assessed in non-clinical testing, stating: "this metabolite has not been adequately evaluated by conventional rules of engagement and I believe this will elicit a negative response." MacDonald explained that the Metabolite had not been qualified due to the inadequate exposure multiples for the toxicology studies and rejected Celgene's representation to the contrary: "Not sure how you [can] say this [i.e., that 273 was

"qualified relative to repeated dose toxicity"] as the E[xposure] M[ultiple] in the carc and reprotox studies is <1 –?"

278. MacDonald testified that Celgene "clearly had a problem" because "[t]he issue of metabolites and differential exposures to metabolites, human specific metabolites is an area of intensive focus.... [s]o it was clear to me when I saw it, that is why I said they had a problem, I referred to that in several of my e-mails, when I said they had a problem, it was recognizing the heightened awareness at the agency of this issue."

279. Saillot forwarded MacDonald's comments to Martin on December 3, 2017. MacDonald also forwarded his response to one of his colleagues, stating that "Jean-Louis [Saillot] and Receptos have a problem—but their FDA/draft NDA docs only show an 'arm-waving' approach to dealing with the problem. Not the sort of client we want to be spending this much time with!"

280. Internally, senior Celgene employees also flagged the non-clinical deficiencies in the NDA based on the FDA's Preliminary Meeting Comments. For example, on November 22, 2017, Lamb sent the Preliminary Meeting Comments to Kumar, stating "FDA is not in agreement with the total agonist approach." Lamb asked, "[w]ith that in mind, is RP112273 qualified across all studies?" adding that the FDA "is expecting a complete nonclinical package with parent and each active [metabolite] qualified across the full battery of studies." Kumar responded, copying Backstrom, stating "[o]ne lingering concern I have is with 2-year rat carci study. . . . Retrospective analysis indicates 2273 exposure multiple is <1 at the high dose. In light of 2273 being an active metabolite, I worry [FDA] might renege on the agreed [study] design and say that we have not fully assessed the risk. Unfortunately, we don't have options here."

12. Defendants Knew or Recklessly Disregarded that Celgene Had Submitted a Deficient NDA at the Time of the January and February 2018 Ozanimod Misstatements

281. As discussed above, prior to December 2017, Defendants knew or recklessly disregarded extensive information showing that the Ozanimod NDA was incomplete and deficient with respect to both the clinical and non-clinical Metabolite data. Defendants had also been expressly warned that these deficiencies could result in a RTF. Notwithstanding this information, Celgene submitted the NDA on December 22, 2017.

282. On January 8, 2018, Celgene issued a press release attached to a Form 8-K announcing its preliminary Q4 2017 and full-year 2017 financial results. The press release touted the "FDA decision on the submission of an NDA for ozanimod in patients with relapsing multiple sclerosis (RMS)" as one of Celgene's "2018 Expected Operational Milestones." On January 25, 2018, Celgene filed another Form 8-K attaching a press release stating that "a New Drug Application (NDA) was submitted with the FDA for Ozanimod in relapsing multiple sclerosis (RMS) based on data from the phase III RADIANCE™ Part B and SUNBEAM™ trials for evaluating Ozanimod in patients with RMS." On February 7, 2018, Celgene filed its 2017 Annual Report on a Form 10-K ("2017 10-K") again representing that "a New Drug Application (NDA) was submitted with the FDA for ozanimod in RMS based on data from the phase III trials evaluating ozanimod in patients with RMS." The 2017 10-K also included a chart representing that the "Status" of Ozanimod for RMS was "Regulatory submission" and that Celgene "Entered current status" in the fourth quarter of 2017.

283. Consistent with Celgene's corporate process for public disclosures, the information regarding the Ozanimod NDA contained in Celgene's January and February 2018 statements was furnished by the I&I franchise, and reviewed by I&I President Curran. Pursuant to Celgene's disclosure process, Smith and Curran received and reviewed draft and proposed final versions of

Celgene's January 8 and 25, 2018 Forms 8-K and the 2017 10-K. Curran also spoke about the Ozanimod NDA during the January 25, 2018 earnings call.

284. At the time of the January and February 2018 statements, Defendants knew that Celgene had failed to provide to the FDA the necessary LTS data to validate the Metabolite samples from the clinical studies. In fact, Celgene submitted only 136 days of LTS data to the FDA for the Metabolite, which was insufficient to cover any of the samples from the 1904, 1905, and 1906 Phase I clinical studies or the 201B and 301 Phase III clinical studies.

285. Defendants also knew that the non-clinical component of the NDA was deficient because the safety multiples from Celgene's toxicology studies were below the FDA-mandated threshold of 1.0 for disproportionate metabolites like 273. For example, the non-clinical safety multiple for the 2-year carcinogenicity study in rats was 0.8; the non-clinical safety multiple for the EFD study in rabbits was 0.03; and the non-clinical safety multiple for the EFD study in rats was 0.1. Moreover, Celgene used dose levels in excess of the MTD in its 6-month mouse carcinogenicity study, which Dr. Guengerich explained invalidated this study. Finally, Celgene included estimated safety multiples, since it did not have actual, validated exposure data for certain of the animal species.

286. Despite knowing or recklessly disregarding that Celgene had submitted a deficient NDA and that a RTF was likely, Defendants failed to disclose any information concerning the Metabolite and the resulting deficiencies in the NDA, or the risks these deficiencies posed to the NDA.

287. Analysts commented on Celgene's NDA filing and projected that the NDA would be approved in 2018.

288. Defendants were motivated to file the Ozanimod NDA despite its known deficiencies and the risk of Celgene receiving a RTF, for several reasons.

289. *First*, Defendants knew that generic versions of Gilenya, another treatment for MS, were set to hit the market in late 2019. If Ozanimod won FDA approval, it could compete directly with Gilenya before generic versions of Gilenya became available

290. *Second*, Defendants knew that Celgene needed the revenues from Ozanimod to replace the revenues that it would lose when Revlimid's patent protection expired.

291. *Third*, Celgene's announcement on October 19, 2017 that it was scrapping development of GED-0301 and Celgene's dramatic reduction in its Otezla sales guidance on October 26, 2017 heightened the importance of Ozanimod to Celgene's future financial success.

292. *Fourth*, Celgene employees, including Defendants Martin, Smith, and Curran, were entitled to receive bonuses if the Ozanimod NDA was submitted before year-end 2017.

293. Houn's testimony confirms that Celgene's motivation to file the NDA by year-end 2017 was not based on the sufficiency of the NDA.

13. The FDA Issued the RTF Due to the Exact Metabolite Data Deficiencies Defendants and the FDA Had Flagged Prior to the NDA Filing

294. On February 23, 2018, the FDA issued an RTF for the Ozanimod NDA submission. The significance of the NDA's deficiencies is demonstrated by the fact that the FDA rarely issues RTF letters, issuing just 45 RTFs in connection with NDA applications between December 31, 2001 and February 28, 2018.

295. There were two bases for the RTF: deficiencies with the clinical data (incomplete LTS data) and deficiencies with the non-clinical data (inadequate safety multiples in toxicology studies). These were the same deficiencies that numerous Celgene employees identified before

the NDA was submitted, and that the FDA flagged in its Preliminary Meeting Comments. As the RTF stated:

> The long-term stability of RP112273, a recently identified predominant and active metabolite of ozanimod, has not yet been established. Retained plasma samples were used to quantify RP112273 in studies RPC01-201 (Part A and B), RPC01-301, RPC01-1904, RPC01-1906 and for most of subjects in study RPC01-1001. The samples were analyzed outside of the long-term stability window (136 days) for RP112273...

296. The RTF further stated:

> RP112273, an active metabolite with potency at the S1P 1 and 5 receptors similar to that of the parent compound, accounts for the majority (~90%) of drug-related material in circulation in humans. Therefore, you will need to demonstrate that RP112273 has been assessed in a standard battery of nonclinical studies.... Based on a preliminary examination, the available TK data are insufficient to allow a determination of the adequacy of the safety assessment for RP112273.

297. On February 27, 2018, Celgene issued a press release, which stated it had received an RTF from the FDA concerning the Ozanimod NDA.

298. Post-RTF correspondence between Celgene and the FDA, including meeting minutes and written responses, confirms that the FDA found Celgene's safety multiples for several of the non-clinical toxicology studies to be inadequate. The minutes from Celgene's April 3, 2018 Type A meeting with the FDA following the issuance of the RTF letter state that "the plasma RP112273 exposures achieved in the mouse and rat carcinogenicity studies are not adequate, in the absence of data indicating higher RP112273 exposures would not be tolerated or feasible to achieve." In its November 9, 2018 written responses to Celgene's August 29, 2018 meeting request, the FDA stated: "The preliminary data summarized in... the briefing package suggest there was insufficient exposure to both [the Metabolite and CC1084037] metabolites in the embryofetal development (EFD) and carcinogenicity studies in rat."

299. With respect to the incomplete LTS data, Celgene documents post-dating the Company's receipt of the RTF confirm that Defendants knew that the NDA was deficient at the time it was submitted in December 2017 because of the missing LTS data. In a February 27, 2018 email to Backstrom and Palmisano, Lamb re-sent Tran's chart summarizing the incomplete LTS data from November 30, 2017, stating: "Some of the studies are complete but we don't have the required sample stability for the RP112273 metabolite. Please see the below table..." In the same email, Lamb confirmed that the FDA never agreed to accept an incomplete NDA and allow Celgene to supplement the NDA with additional LTS data after the December 2017 submission. Lamb stated: "FDA didn't agree to anything and they stated repeatedly that the CSRs [clinical study reports], BARs and stability data needed to be in the original submission. Even in a subsequent email exchange FDA stated reports needed to be submitted at [] the time of the NDA submission (not within 30 days which we proposed via email)."

300. Tran corroborated Lamb's statements in a February 27, 2018 email to Palmisano. Tran wrote: "[T]he FDA wanted LTS data and would not accept those during the NDA review. In the pre-NDA feedback, the FDA specifically requested LTS data for studies 1001 (PK/PD in RMS), 1904 (hepatic impairment) and 1906 (renal impairment)." Palmisano forwarded Tran's email to Rupert Vessey, Celgene's president of Research and Early Development. Vessey responded that going forward, "you, Gondi [Kumar] and I must approve of anything that is sent in. Philippe [Martin] must not be allowed to be the final decision maker as he was in the case of not proceeding with the preNDA meeting." Palmisano agreed.

301. On March 15, 2018, Michael Faletto, Celgene's Executive Director of Regulatory Knowledge and Insights asked Lamb to speak at an upcoming Celgene Regulatory Affairs meeting regarding the Ozanimod RTF. Lamb indicated he would be "happy to speak to ozanimod and the

RTF[,]" but "[t]here isn't much to learn from a Regulatory Affairs perspective. FDA repeatedly stated what they expected, it was ignored and we got a RTF."

302. On April 3, 2018, Curran gave a presentation to Celgene's Board of Directors describing the circumstances leading to the Ozanimod RTF. One of the slides was entitled "Ozanimod-Related Correspondence with FDA", and stated: "Feb 2018:... FDA issues Refusal to File Letter, identifying nonclinical and clin pharm deficiencies consistent with the pre-NDA meeting feedback."

303. Houn likewise testified that she was not surprised that Celgene received the RTF because FDA had clearly told Celgene in November 2017 what data was required to be submitted with the NDA: "I wasn't surprised, because unless those studies were completed and put into the NDA, FDA had stated in November that, you know, that they are a requirement at the time of submission."

304. In a May 10, 2018 presentation sent to Lamb, Kumar summarized the "sequence of events" leading to the RTF. The presentation listed the FDA's "Pre-NDA Nonclinical comments" regarding the need for adequate exposure multiple data, the deficient exposure multiple data Celgene included in the NDA, and the RTF's finding that the exposure multiple data was insufficient.

305. In late April 2018, Celgene disclosed the Metabolite. Specifically, on April 25, 2018, several scientists gave a presentation at the American Association of Neurology ("AAN") 2018 Annual Meeting in Las Vegas, Nevada that was partially funded by Celgene. This presentation disclosed to investors certain specifics of the Ozanimod metabolite CC112273, stating: "Ozanimod is metabolized in humans to form one major active and other minor active

metabolites"; "CC112273 accounts for the majority of the total activity of ozanimod in humans"; and "CC112273 is a minor metabolite in animal species."

306. Following the receipt of the RTF letter, Celgene reorganized its corporate structure, which resulted in the elimination of Martin's and Smith's positions.

307. Smith departed Celgene on April 2, 2018.

308. Martin left Celgene in June 2018.

14. Celgene Was Required to Submit Additional Clinical and Non-Clinical Data for the Metabolite When it Resubmitted the Ozanimod NDA in March 2019

309. On April 3, 2018, Celgene had a Type A meeting with the FDA to discuss Celgene's proposal for addressing the deficiencies identified in the RTF.

310. Celgene did not resubmit the NDA until March 25, 2019. The resubmitted NDA ("rNDA") included additional clinical and non-clinical data for the Metabolite to address the deficiencies in the NDA.

311. With respect to the clinical data, when Celgene submitted the rNDA in March 2019 (over a year after receiving the RTF), it included 17 months of LTS data for 273. These 17 months of data "cover[ed] all the retained and fresh samples used to analyze RP112273 in the relevant Phase 1 studies... which provide full characterization of RP112273 PK and PK/PD properties." With respect to the Phase III studies, the "17-month LTS data cover[ed] the vast majority of samples collected at the month 12 time point in RPC-301 (~99% of samples...) and at month 24 in RPC01-201B (~98% of samples)." In addition, Celgene conducted assessments "comparing RP112273 concentrations over days of sample storage in studies RPC01-201B and RPC01-301 [i.e., the Phase III studies]" and found "no clear upward or downward trend." In the FDA's review file for the rNDA, the FDA noted that it only considered samples "within the stability window for

RP112273 (17 months)" and thus did not consider the Phase III samples that were outside of the 17-month window.

312. With respect to the non-clinical data, Celgene provided "[a]dditional data on exposure to the major human metabolites in the nonclinical studies" in the rNDA.

313. In its March 9, 2018 Type A Meeting Request submitted to the FDA, Celgene stated:

> To address the Division's request to bridge RP112273 exposure to nonclinical safety studies, Celgene is proposing GLP-compliant repeated ozanimod dose pharmacokinetic studies in the mouse and monkey... that are supported by formal RP112273 plasma stability. Ozanimod will be orally administered daily, for up to 14 days to both male and female animals. The ozanimod dose levels administered will be the same as those dose levels from the respective toxicity studies at both the NOAEL and the highest dose tested....
>
> Finally, as the exposure of RP112273 was low in rabbits administered ozanimod, GLP-compliant embryo-fetal studies have been initiated with RP112273 administration to the rabbit, including plasma analysis....

314. In addition to the bridging studies and the new rabbit EFD studies, Celgene also initiated a 28-day mouse repeated dose study. Celgene told the FDA that the reports from these new studies "would be available for the re-submission" of the NDA.

B. Plaintiff intends to prove the following contested facts with regard to damages: (This must include each item of damages, the amount of each item, the factual basis for each item and, if punitive damages are claimed, the facts upon which plaintiff will rely to establish punitive damages).

1. Dr. David I. Tabak, Plaintiff's economic expert, calculated the damages Plaintiff and the Class suffered using a standard "out-of-pocket" damages model that measures the degree by which the market price for Celgene's common stock was inflated as a result of Defendants' false or misleading statements and omissions.

2. Dr. Tabak first determined that Celgene stock traded in an efficient market during the Class Period, and then calculated the artificial inflation maintained by Defendants' false or

misleading statements and omissions by measuring the reaction of Celgene's common stock price to disclosures that corrected these false or misleading statements and omissions. In doing so, Dr. Tabak employed a statistical technique known as an "event study." After controlling for market and industry factors and accounting for any potentially confounding news released on the corrective disclosure dates, Dr. Tabak "backcasted" the price reaction in Celgene's stock following these corrective disclosures to earlier points during the Class Period, thereby measuring the amount of inflation maintained by Defendants' false or misleading statements and omissions.

3. The corrective disclosure for the April and July 2017 Otezla False Statements occurred on October 26, 2017, when "Celgene stunned the market by announcing that, in light of the dismal Otezla sales numbers, the Company had slashed the 2017 guidance by more than $250 million—providing updated guidance of $1.25 billion compared to the $1.5 billion to $1.7 billion range Defendants reaffirmed just weeks earlier." Because the "variables affecting OTEZLA's Q3 performance are expected to continue to put pressure on its near-term growth profile," Celgene adjusted its Otezla public guidance through 2020, as well. Celgene attributed its guidance reduction to overall market deceleration, its inability to execute its managed care strategy, negative market share impacts related to patients previously exposed to biologics, and inventory fluctuation. These factors existed prior to both the April and July 2017 Otezla False Statements. Celgene's claim that an overall market deceleration drove the Otezla guidance reduction, however, was simply false. In fact, competitor companies explained in public disclosures that rather than a market *de*celeration, the overall market growth had accelerated when stripping out Otezla-specific poor performance.

4. The October 26, 2017 corrective disclosure corrected the April and July 2017 Otezla False Statements by demonstrating that prior statements about Otezla's performance

metrics – and projections using those metrics – had been false or misleading and omitted facts that were material to investors. This corrective disclosure further informed the market that market size, market share, market growth, market access/managed care contracting, prescriber adoption, inventory, and demand metrics directly contributed to Celgene's decision to lower its guidance, and that such issues persisted both during – and before – the third quarter of 2017. Celgene, other pharmaceutical companies in the industry, and investors all considered these metrics key indicators of Otezla's performance.

5. Multiple analysts reacted negatively to the news of Otezla's lowered guidance through 2020, including, for example: Leerink Partners, noting that Otezla faced "negative market trends"; J.P. Morgan, assessing that Celgene's management "faces a major credibility issue" and that "lackluster Rx trends" exceeded expectations; BMO Capital Markets, observing that Otezla failed to "offset the aggressive discounting and slowing growth of psoriatic arthritis and greater competition in the psoriasis markets"; and BTIG Equity Research, writing that Celgene "severely disappointed relative to expectations on Otezla."

6. An internal document prepared for Celgene's Board of Directors further identified "OTEZLA's poor performance versus our forecast" as a reason why the Company decided "to lower and communicate changes to our long-standing 2020 financial outlook."

7. After determining that Celgene traded in an efficient market and controlling for the effect of general market and/or industry factors on Celgene's stock, Dr. Tabak determined that the $18.72 price decline following the October 26, 2017 corrective disclosure was statistically significant.

8. To determine the share of the change in the market's valuation of Celgene due to the changes in its views of Otezla, as opposed to other reasons, Dr. Tabak compiled and analyzed

analyst reports containing estimates for Otezla sales and for overall revenues both before and after October 26, 2017.

9. The average analyst estimate for Celgene's total revenue in 2017 went from $13.23 billion before the October 26, 2017 disclosure to $12.95 billion afterwards, a decline of $279 million. Of this, $219 million is attributable to declines in expectations for Otezla, based on the change in estimates for Otezla sales from those same analyst reports.

10. As most of the value for Otezla will be found in the final year of the forecast, as that is the basis for forecasting out into the future (and thus accounts for not just one year of forecasts, but the present value of all of those years), Dr. Tabak attributes approximately two-thirds of the $18.72 price reaction (the average based on the 2021 forecasts), or $12.37, to the news regarding Otezla.

11. To scale the inflation figure over time based on what Defendants could have disclosed as of the date of each Otezla misstatement, Dr. Tabak created a chart that measured daily predicted Otezla sales relative to the midpoint of Otezla's 2017 Public Guidance ($1.6 billion) under three projections ("YTD percentage," "1-Week Rolling Average Sales," and "4-Week Rolling Average Sales"). The chart calculates, on a daily basis, the shortfall of the predicted sales under each projection to the average of the stated guidance range of $1.6 billion, representing the negative surprise in guidance that Celgene could have announced on each date had it changed its guidance from $1.6 billion to a figure supported by the internal data.

12. Applying a methodology to review reported daily sales in the calculation of rolling average sales over a four-week period, the relevant negative guidance surprises that could have been announced on the misrepresentation dates of April 27, 2017 and July 27, 2017 are $0.47 billion and $0.51 billion, respectively. These represent 133% and 146% of the negative guidance

surprise of $0.35 billion announced on October 26, 2017. To be conservative, Dr. Tabak did not increase the actual downward guidance given on October 26, 2017 for earlier dates.

13. As it is Dr. Tabak's understanding that the Class in this matter cannot recover more than the inflation that they paid for, for purposes of calculating damages, Dr. Tabak limited this component of the inflation to $12.37 over this period. Using the four-week methodology in reported year-to-date sales in the calculation of rolling average sales yields similar results, with inflation attributable to the October 26, 2017 disclosure of $18.02 and $19.61 over the two subperiods, which Dr. Tabak again limits to $12.37. As both methodologies yield the same results, Dr. Tabak's further analyses treat the inflation related to the October 26, 2017 disclosure as equal to $12.37 per share from April 27, 2017 through October 25, 2017.

14. The statistically significant stock-price decline identified above indicates that the information in the October 26, 2017 corrective disclosure was new, material information that constructively disclosed the fraud and caused losses to investors.

15. Dr. Tabak identified two corrective disclosures related to Defendants' false or misleading statements and omissions regarding Ozanimod. The first corrective disclosure occurred on February 27, 2018, when Celgene announced that it had received a RTF letter from the FDA related to the Ozanimod NDA, leading to a $7.77 abnormal price decline. The second corrective disclosure occurred on April 29, 2018, when Morgan Stanley revealed that resubmission of the NDA would be delayed by up to three years based on newly acquired information regarding the concentration of the Metabolite and the heightened potential need for new clinical studies, leading to a $2.82 abnormal price decline. The closing price of Celgene's common stock on April 27, 2018 was $91.18 per share, and the closing price of Celgene's common stock on April 30, 2018 was $87.10 per share. Dr. Tabak determined that the price declines on both dates were statistically

significant at the 95% confidence level, which indicates that the corrective disclosures revealed material information and caused losses to investors. Dr. Tabak further determined that "[t]hese losses were caused by Defendants' allegedly improper failure to disclose evidence of the Metabolite and meaningful information about that evidence relevant to the NDA submission."

16. Dr. Tabak determined that Celgene's February 27, 2018 disclosure was corrective of Defendants' misstatements and omissions regarding the Metabolite because it "indicated one or more severe deficiencies [in the Ozanimod NDA that were related to the Metabolite] that Plaintiff alleges were known or recklessly disregarded by Defendants." In calculating the amount of artificial inflation associated with the February 27, 2018 corrective disclosure, Dr. Tabak determined that "there is no need to adjust the inflation measured from this corrective disclosure for any changes in Defendants' knowledge over time" because Plaintiff "alleges that Defendants had evidence of the Metabolite as of the date of the first Ozanimod misrepresentation," and "[i]f Lead Plaintiff's allegations are correct, once Celgene had evidence of the Metabolite, Defendants' publicly touted timeline for submission of the NDA was no longer tenable." However, Dr. Tabak opined that in the event the fact-finder determines that there is a need to adjust inflation to account for changes in Defendants' knowledge over time, "there are ways mathematically to adjust for that" i.e., the fact-finder "could scale down the inflation... based on the difference between the market perception and the company perception."

17. Dr. Tabak determined that the level of inflation associated with the February 27, 2018 corrective disclosure should be adjusted to reflect the anticipated size of the Ozanimod market following FDA approval of Ozanimod. Dr. Tabak identified two analyst firms that regularly published forecasts of 2021 Ozanimod sales prior to the February 27, 2018 corrective disclosure and adjusted the February 27, 2018 abnormal decline of $7.77 per share to reflect these

analysts' varying estimates of Ozanimod sales. Dr. Tabak's calculations of daily inflation based on this adjustment is produced in Exhibit 7 of his May 11, 2022 expert report.

18. Dr. Tabak determined that the April 29, 2018 Morgan Stanley report was corrective of Defendants' misstatements and omissions regarding the Metabolite because it provided "a detailed analysis revealing [Morgan Stanley's] estimate of the effects of the Metabolite on the approval process for Ozanimod, including the heightened potential need for new clinical studies." Since it took Morgan Stanley four days to collect and analyze information about the Metabolite, Dr. Tabak determined that inflation for the abnormal $2.82 price decline associated with the April 29, 2018 corrective disclosure should begin four days after the first alleged misrepresentation or omission.

19. Dr. Tabak determined that there was no need to adjust his measure of inflation associated with the April 29, 2018 corrective disclosure based on analyst estimates of potential Ozanimod sales because analyst estimates of 2021 Ozanimod sales before the April 29, 2018 corrective disclosure were higher than the most recent estimate preceding the corrective disclosure, i.e., any adjustment would have increased inflation beyond the actual price decline associated with this corrective disclosure.

V. DEFENDANTS' CONTESTED FACTS (State separately for each Defendant. (See instructions **above**).[2]

A. Defendants Celgene and Curran intend to prove the following contested facts with regard to alleged liability for Otezla.

Contrary to Plaintiff's allegations, Defendant Terrie Curran did not make any false or misleading statements regarding Otezla. Indeed, Curran's two statements, one in April 2017 and

[2] Defendants object to the relevancy and accuracy of many of Plaintiff's Contested Facts. Additionally, Defendants incorporate by reference here, the contents of Defendants' other submissions that form part of the Pretrial Order, including but not limited to, Defendants' exhibits

the other in July 2017, were accurate when made. Based on the information Curran received about Otezla prior to making her statements, she believed that the statements were true and accurate at the time she made them and she was not reckless in making the statements. Curran had no intention of misleading investors when she made her statements and she had no motive to mislead investors. Furthermore, Plaintiff cannot meet its burden of showing that it suffered any damages as a result of Curran's statements. For all of these reasons, Plaintiff's Otezla claims must fail.

1. Relevant Background

The following background is necessary to correct Plaintiff's grim and inaccurate depiction of Otezla and provide the proper context for considering Curran's Otezla statements.

1. Plaintiff AMF is a Swedish pension fund "giant." It manages the pensions of over four million customers in Sweden and has grown from 594.7 SEK billion (~$56.8 billion) assets under management in 2017 to 734 SEK billion (~$70.2 billion) in 2022.

2. Celgene is a global biopharmaceutical company engaged in the discovery, development, and commercialization of therapies to treat cancers and inflammatory diseases. During the relevant time period, Celgene invested substantially in research and development in support of multiple ongoing proprietary clinical development programs which support its existing products and pipeline of new drug candidates.

3. Curran has dedicated her career to working in the pharmaceutical industry. Curran started as a sales representative at Upjohn, worked her way up to managerial positions at Pharmacia, Schering-Plough, and Essex Chemie, and then ran the women's health business globally at Merck. Curran joined Celgene in 2013 as the Corporate Vice President U.S.A. in

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and expert reports, and the non-inclusion of any facts in those materials in the present document is not a waiver of Defendants' rights to raise any such facts at trial. Furthermore, Defendants reserve the right to amend these Contested Facts without limitation at any time before trial, including in connection with the Final Pretrial Order.

preparation for the launch of Otezla. In March 2016, Curran became the Head of Celgene World Wide Markets I&I. On April 1, 2017, she became the President of Celgene I&I and the Chairwoman of the Inflammation and Immunology Executive Committee ("IIEC"), which made strategic decisions and oversaw I&I's business operations.

2. Otezla Was Approved by the FDA as the First Oral Therapy to Treat Psoriatic Arthritis and Plaque Psoriasis Without a Safety-Related Warning

4. During the relevant time period, patients suffering from psoriatic arthritis ("PsA") and psoriasis ("PsO") had several treatment options, which were more or less appropriate for different patients depending on the severity of the patient's condition and the patient's preferences.

5. Topicals are the most frequently used treatment for PsO and are often used to treat mild to moderate cases. Topicals are not typically used alone to treat PsA (sometimes they are used in conjunction with other treatments). Topicals vary in strength and form and are available both over-the-counter and by prescription.

6. By contrast, systemic treatments are often used for patients with moderate to severe PsO and PsA who are not responsive to topicals or have difficulty tolerating them. Traditional systemic therapies include drugs such as methotrexate, cyclosporine, and acitretin, which are generic DMARDs.

7. The DMARD methotrexate is commonly used as the first step in treating PsA and is associated with liver and kidney risks and cannot be taken during pregnancy.

8. Biologics are another form of systemic treatment besides DMARDs. Biologics, such as Humira, Enbrel, and Stelara, are administered by injection or intravenous infusion. They are often tried for PsO and PsA, after other treatments fail, or for patients who have trouble tolerating other treatments.

9. Otezla is an oral systemic treatment that can be safely prescribed to patients already on methotrexate and/or biologics who have not had an optimal therapeutic response. As a treatment option, Otezla is appropriately compared to other oral agents, not biologics, as Otezla and biologic agents are used for different subsets of patients. Otezla is also appropriately compared to the first category of treatments, topical agents and phototherapy, because of their shared convenience, safety, and lack of interactions with other drugs.

10. Otezla is an effective treatment for PsO and PsA. According to Dr. Gary Solomon (Director, NYU Langone Center for Arthritis & Autoimmunology), "[d]uring the Class Period, there was ample published evidence to support the efficacy of Otezla as a treatment for both psoriasis and psoriatic arthritis, and the product was indeed widely used during that period."

11. Dr. Solomon also opined that "Otezla is safer than any of the other available DMARDs or biologic therapies." Unlike Otezla, biologics are immunosuppressant drugs, which present increased risks to patients, such as infection, cancer, cardiovascular disease, and bone marrow suppression, and may require increased clinical monitoring. Due to the increased risks of such serious side effects from these biologic drugs, they are required to include in their labels a black box warning, which is a safety-related warning assigned by the FDA to warn consumers about the major risks of the drug. A black box warning conveys that the FDA determined that the product carries greater potential safety risks than a product that does not have such a warning.

12. In contrast to biologics, Otezla does not present the same risks of side effects because it is a less immune-suppressing drug. Indeed, in 2016 and 2017, Otezla was the only oral therapy available on the market that was indicated for psoriasis and did not have a black box warning.

13. In addition, many patients preferred Otezla's oral administration so as to avoid treatments administered with an injection or intravenously, like biologics. Likewise, Otezla's oral form offered an alternative to topicals, which can include aggressive treatments with coal tar derivatives that are messy and can stain clothing and bathroom appliances. Otezla also offered an alternative to phototherapy, which requires frequent visits (up to three times a week), is costly in terms of direct costs and time away from work, and, in the past, has been associated with a high rate of skin cancer.

14. According to Dr. Solomon, "Otezla is highly appealing to dermatologists," a type of doctor that treats patients with PsO, "because of Otezla's safety, oral route of administration, and lack of need for laboratory monitoring." Otezla likewise is a suitable treatment for specific subtypes of psoriasis, including scalp, face, nails, and palmar-plantar psoriasis. Dermatologists are the major prescribers of Otezla.

15. In addition, "Otezla is desirable for a subset of rheumatology patients" treated by rheumatologists, a type of doctors that treats patients with PsA, because "it can be used in combination with other systemic drugs such as methotrexate"; it can be "used in combination with patients on biologic therapy"; and "it is suitable for patients who are immune compromised."

16. Otezla's central marketing message was not its efficacy or its potency. Instead, Otezla's product differentiation was predicated on being "safer and easier to administer than the competing therapies and . . . reasonably effective in the disease areas that it was indicated for." Otezla was positioned as the "Safe," "Easy," "Oral" option for patients who desired a better safety profile and convenience and were not ready for biologics. "For its intended patient population, Otezla is an appealing medication," and "its safety and ease of administration serve to make it an appealing therapeutic option for physicians and a select group of patients."

17. Given Otezla's safety profile, ease of use and greater convenience, Celgene identified that one of Otezla's main market opportunities would come from "[i]ncreasing usage with pre-biologic patients" and positioned Otezla's brand as a first line of treatment for that reason. That brand positioning strategy targeted a large segment of the PsO and PsA markets and offered substantial growth potential for Otezla.

3. Otezla Achieved Blockbuster Status in Record Time

18. In 2015, Otezla grew 485% in unit sales, 576% in gross revenue and 528% in net revenue in the U.S. market.

19. In 2016, Otezla grew 88% in unit sales, 121% in gross revenue, and 105% in net revenue in the U.S. market.

20. Also in 2016, Otezla achieved the milestone of sales in excess of $1 billion since launch, which is referred to as "blockbuster status." It did so faster than its branded competitors such as Humira, Stelara, Enbrel, and Remicade.

4. Celgene Increased Market Access for Otezla by Successfully Contracting with Three Large Payors to Remove Biologic Step-Edit Restrictions

21. In 2016, Celgene undertook a strategy to increase market access for Otezla by negotiating with health insurers and pharmacy benefit managers ("PBMs"), with whom health insurers contract to help manage their prescription drug benefits, for better insurance coverage for Otezla in return for discounts on Otezla. This was a common industry strategy.

22. Health insurers often do not pay the full cost of all drugs that patients are prescribed by their doctors. To control prescription costs for payers, health insurers and PBMs often use utilization management tools, such as formularies, prior authorizations, and "step therapies." "Step therapies" or "step edits" require patients to try one drug before trying another.

23. According to Robert Tessarolo (Vice President, General Manager of I&I in the U.S.), it made "good business sense" to contract with payers to remove step-edit restrictions, because "more broad coverage increases the volume of your business, which generally offsets the discount that you provide." Over the long term, the contracting will "create the most value for Celgene and our shareholders and our patients." Celgene "thought [it] had the best plan possible to drive success." Similarly, Hunter Smith (Vice President of Finance for the I&I franchise), testified that while Otezla already had experienced very meaningful market share growth since it came on the market, the managed care removal of step edits allowed Celgene the opportunity to further increase Otezla's market share.

24. As part of Celgene's strategy to increase patient access to Otezla, in late 2016, it successfully negotiated contracts with three large payors—ESI, Prime Therapeutics ("Prime"), and Aetna, which removed the requirement that patients try biologic competitors before using Otezla in return for discounts on Otezla. Given the size of these payors, the agreements with ESI, Prime and Aetna increased Otezla's bio-step free access from 30 percent of U.S. commercial lives (*i.e.*, patients who are members of a private insurance plan) in 2016 to 58 percent in 2017.

25. Celgene expected that given Otezla's well documented and differentiated product profile in terms of safety, convenience of use, and high brand awareness, an increase in formulary coverage could significantly and positively impact Otezla net sales in 2017. Celgene anticipated that the contracts would result in a positive net sales impact for FY 2017 (three managed care contracting options were "expected to increase Otezla's net sales in [FY] 2017" by $2.8 million to $24.6 million). Furthermore, throughout 2017, Celgene continued to pursue contracts with additional plan sponsors and PBMs, such as Cigna, Anthem, CVS Caremark, Humana, and Optum/RX United. In April 2017, Celgene successfully negotiated a contract with Select Health

UT, and by July 2017, Celgene successfully negotiated a contract with Cigna. As a result of these new contracts, Otezla's bio-step free market access expanded even further; taking into account these contracts, more than 62 percent of all commercially insured patients had bio-step free access to Otezla.

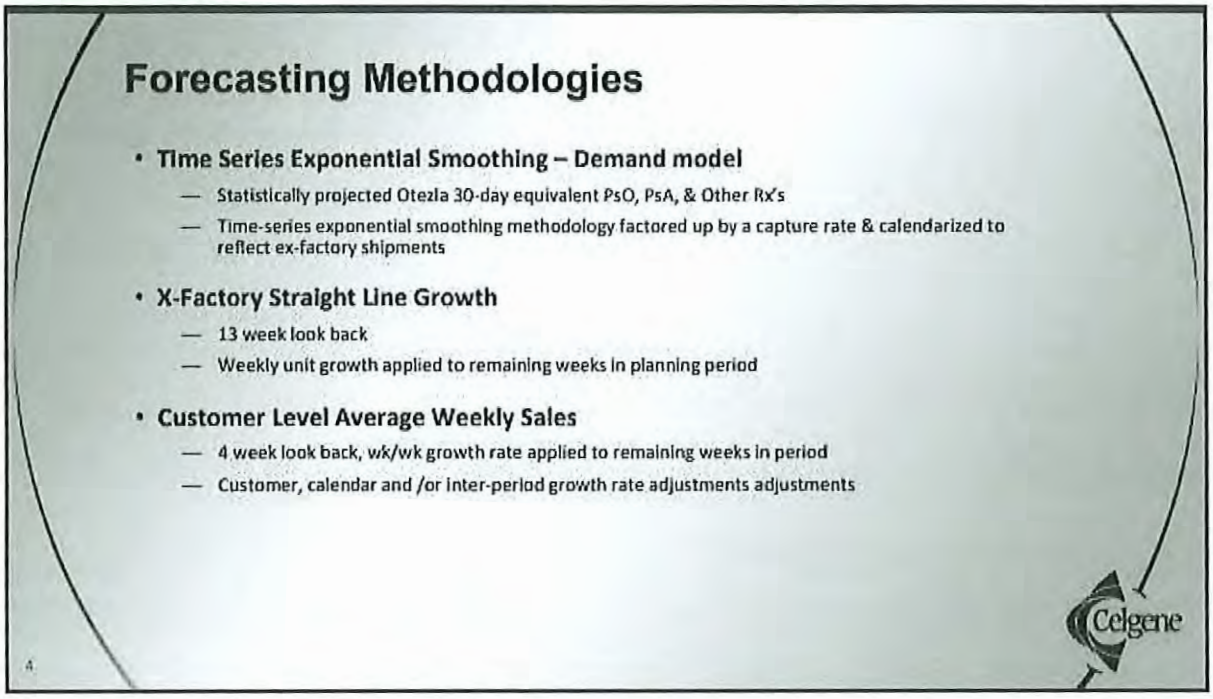
26. By the end of 2017, Celgene had significantly expanded bio-step free market access for Otezla. While only 33 percent of patients had bio-step free access to Otezla in 2016, 75 percent of all commercially insured patients had bio-step free access to Otezla by the end of 2017.

5. Celgene Prepared the 2017 Budget in Line with Industry Standards

27. The 2017 Otezla budget process began in or around September 2016.

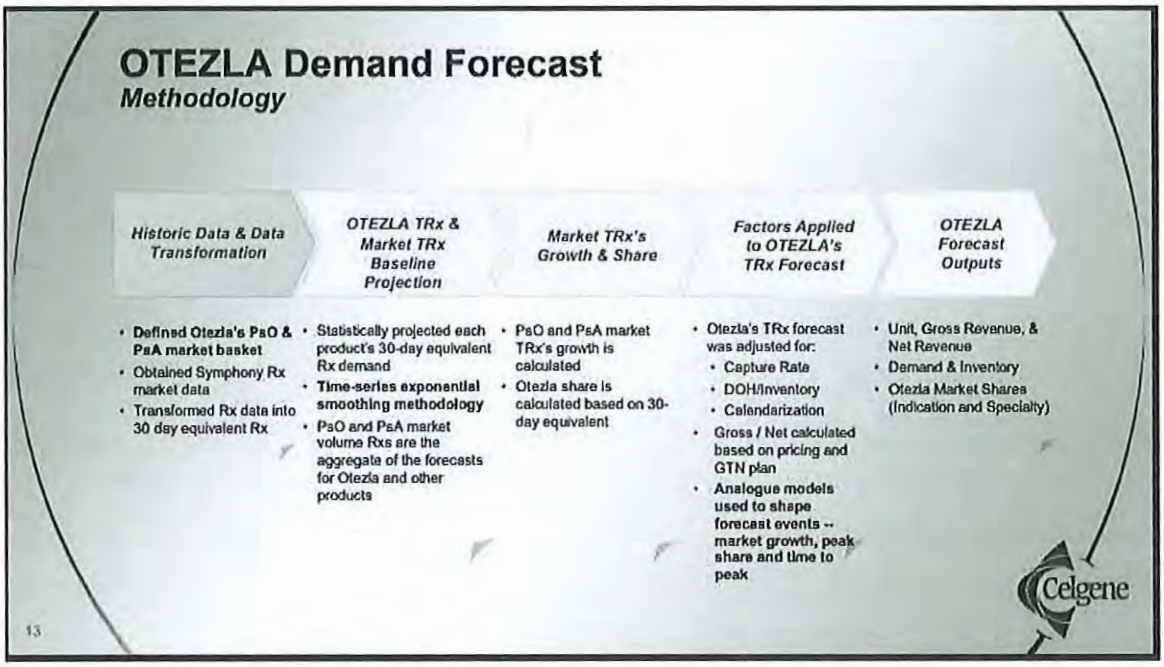
28. In preparing the 2017 Otezla budget, Celgene adhered to well-accepted pharmaceutical industry performance assessment and forecasting principles.

29. Celgene's forecasting methodologies used to create Otezla's 2017 budget and perform subsequent quarterly performance evaluations relied upon actual market data, in line with industry standards and academic literature. Celgene relied on internal data and the external data from third-party vendors, such as Symphony Health, to track Otezla and other products' total prescriptions as well as the number of new prescriptions filled for treatment of PsO and PsA. This data was used as inputs to three independent models used to analyze historical trends and to make projections for Otezla and other products:



30. These three models were analyzed separately and provided different viewpoints of forecasted demand. The first method was a time-series exponential smoothing model of demand, a statistical technique commonly used in pharmaceutical forecasting to eliminate short-term random fluctuations from sales trends. The second method, "X-Factory Straight Line Growth" model, applied the historical weekly shipment growth rate in the previous quarter to forecast future shipments. The third method, "Customer-Level Average Weekly Sales" model, looked back four weeks to infer how much customer demand had grown during that time frame and applied that growth rate on a "forward-looking basis" for its forecast. These data-driven projections were based on real world data. These models did not use market shares as inputs, nor did they include any explicit assumptions about market shares. Market share predictions were outcomes of the forecasting.

31. An early version of the Otezla 2017 budget presentation illustrates the forecast process used by Celgene, starting from data collection through the generation of the output of such projections—*i.e.*, units, gross revenue, net revenue, demand and inventory:



32. As the first step, Celgene considered some established and new products in the PsO and PsA market baskets. After gathering internal and third-party data on historical sales, Celgene projected statistically 30-day equivalent prescription demand for each product in the market basket. The projected market volume for each indication was built up from the forecasted volume for Otezla and for all other products in the market basket. Next, Celgene applied several adjustments to the demand forecast, including adjustments for capture rate (the rate of prescriptions written to prescriptions dispensed), the current size of inventory (measured by days on hand), and calendarization to control for any seasonality based on historical trends.

33. Celgene's projections accounted for ex-trend events, *i.e.*, events that may affect future sales but are not incorporated into historical data, such as the entry of new products, changes in market access, or updates to marketing strategy, consistent with standard practice and academic

literature. Celgene also accounted for the expansion in market access through deals with certain payors and TV advertising spending in its forecasts.

34. Although Celgene's sales projections for Otezla and its competitors were based on real-world data, the company also pressure-tested its long-range market share estimates using analogue research provided by the commercial team and separate from the actual data analysis. Specifically, Celgene's commercial group hired a third-party consultancy named Foster-Rosenblatt to, among other things, develop analogue research to validate Otezla's peak market share 5-10 years post-launch and evaluate the impact of potential new indications. In the research study, Foster-Rosenblatt identified a basket of analogues chosen to match characteristics of Otezla in terms of indication, launch year, 2015 US Sales, US market size, efficacy and safety, market placement, mechanism of action, and convenience improvement, among others. Based on the selection of analogues, Foster-Rosenblatt projected Otezla's peak market share and market growth and calculated the average yearly analogue market share since product launch.

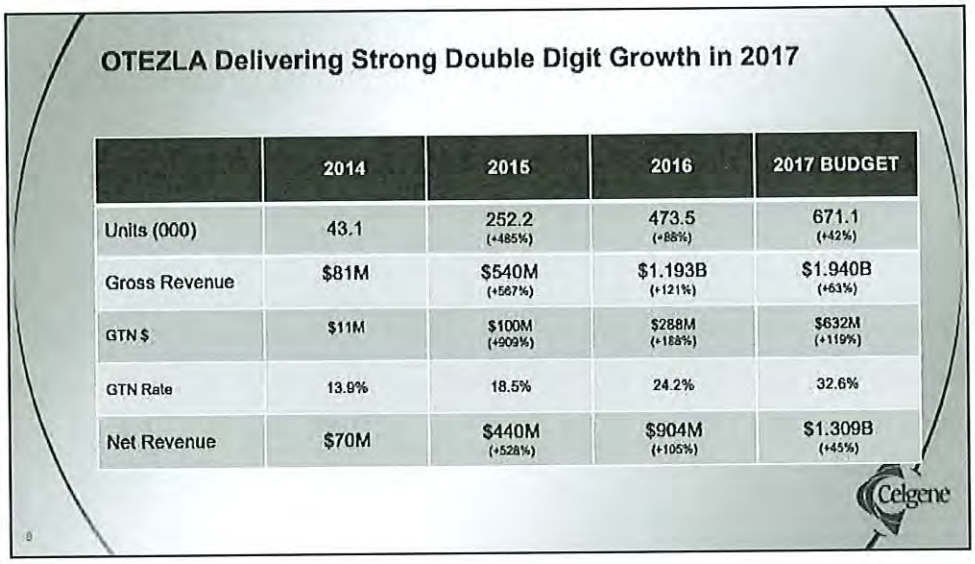
35. As reflected in a September 2016 budget presentation, Celgene compared its internal peak market share and growth forecasts with those of Foster-Rosenblatt's study. Celgene concluded that Otezla's projected market shares for PsO were in line with the analogue analysis, which indicated Otezla had the potential to become the market leader in PsO by 2022. Celgene determined that Otezla's PsA market share would not achieve Foster-Rosenblatt's estimations but that nonetheless, Otezla would reach the number two position in PsA by 2021.

6. Celgene's 2017 Budget Predicted $1.574B in Sales While Accounting for Risks and Natural Deceleration in Growth

36. In January 2017, when Celgene finalized the 2017 budget for Otezla, Celgene reasonably projected worldwide net revenue for Otezla in 2017 of $1.574 billion broken down by

quarter as follows: $302 million in Q1, $377 million in Q2, $420.5 million in Q3, and $474.7 million in Q4.

37. Celgene's budget projections for 2017 represented 42% growth in unit sales, 63% growth in gross revenue, and 45% growth in net revenue in the U.S.—which was significantly less than Otezla's growth in the U.S. in 2015 and 2016:

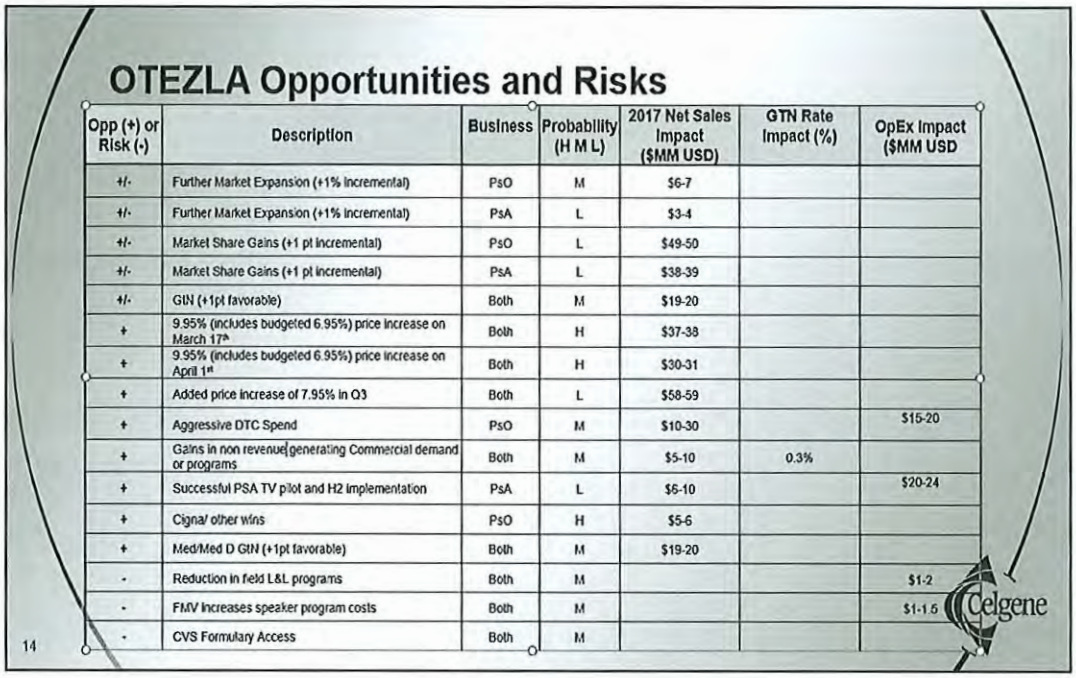


OTEZLA Delivering Strong Double Digit Growth in 2017

	2014	2015	2016	2017 BUDGET
Units (000)	43.1	252.2 (+485%)	473.5 (+88%)	671.1 (+42%)
Gross Revenue	$81M	$540M (+567%)	$1.193B (+121%)	$1.940B (+63%)
GTN $	$11M	$100M (+909%)	$288M (+188%)	$632M (+119%)
GTN Rate	13.9%	18.5%	24.2%	32.6%
Net Revenue	$70M	$440M (+528%)	$904M (+105%)	$1.309B (+45%)

Celgene

38. Celgene also accounted for known risks to its predicted sales. Celgene identified and considered various "[o]pportunities" and "[r]isks" that could impact Otezla net sales in 2017, including risks relating to market expansion, market share, and payor contracts:



OTEZLA Opportunities and Risks

Opp (+) or Risk (-)	Description	Business	Probability (H M L)	2017 Net Sales Impact ($MM USD)	GTN Rate Impact (%)	OpEx Impact ($MM USD
+/-	Further Market Expansion (+1% incremental)	PsO	M	$6-7		
+/-	Further Market Expansion (+1% incremental)	PsA	L	$3-4		
+/-	Market Share Gains (+1 pt incremental)	PsO	L	$49-50		
+/-	Market Share Gains (+1 pt incremental)	PsA	L	$38-39		
+/-	GtN (+1pt favorable)	Both	M	$19-20		
+	9.95% (includes budgeted 6.95%) price increase on March 17th	Both	H	$37-38		
+	9.95% (includes budgeted 6.95%) price increase on April 1st	Both	H	$30-31		
+	Added price increase of 7.95% in Q3	Both	L	$58-59		
+	Aggressive DTC Spend	PsO	M	$10-30		$15-20
+	Gains in non revenue generating Commercial demand or programs	Both	M	$5-10	0.3%	
+	Successful PSA TV pilot and H2 implementation	PsA	L	$6-10		$20-24
+	Cigna/ other wins	PsO	H	$5-6		
+	Med/Med D GtN (+1pt favorable)	Both	M	$19-20		
-	Reduction in field L&L programs	Both	M			$1-2
-	FMV increases speaker program costs	Both	M			$1-1.5
-	CVS Formulary Access	Both	M			

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Celgene

7. Celgene Executives Reasonably Believed that Otezla Would Achieve the 2017 Budget Projections

39. Every fiscal quarter, Celgene executives discussed Celgene's public sales guidance, evaluated the metrics that went into it, and assessed whether there was a need to make adjustments.

40. As part of this evaluation process, in January 2017, Celgene determined to refine its public guidance for Otezla. On January 9, 2017, around the time Celgene finalized its 2017 budget, Celgene issued a press release announcing that it was updating its sales guidance for Otezla, and that it expected Otezla net sales of approximately "$1.5 [billion] to $1.7 [billion]" in 2017.

41. Throughout 2017, numerous Celgene executives, including finance professionals like Peter Kellogg, Celgene's Chief Financial Officer, continued to receive and evaluate detailed data concerning Otezla's sales performance. And though Celgene determined in January 2017 that an adjustment to its 2017 Otezla guidance was warranted, and indeed made such an adjustment, at

no point in the first and second fiscal quarters of 2017 did Celgene's executive team determine there was a need to again refine the guidance.

42. Curran, specifically, was never advised or warned by any Celgene employee that the guidance should be lowered. Contrary to AMF's allegations, Tessarolo testified that he never "warned the IIEC that the guidance should be lowered." Indeed, Tessarolo had no "involvement with" or "discussions around guidance." Tessarolo testified that before he resigned from Celgene in March 2017, Tessarolo had no concern whatsoever that Celgene would not be able to meet its 2017 Otezla sales forecast, and Tessarolo's departure from Celgene was unrelated to any specific incident or concern concerning Otezla's performance.

8. Despite Q1 2017 Challenges, Otezla Exited Q1 2017 Strong and Net Sales Remained on Track to Achieve the Guidance

43. In December 2016, in anticipation of an Otezla price increase in January 2017, wholesalers accumulated "larger than normal" inventory levels of Otezla, which had the effect of depressing Q1 2017 Otezla sales until the wholesalers had drawn down the excess inventories and resumed purchasing Otezla.

44. As of January 23, 2017, Otezla's month-to-date U.S. net revenue and unit sales were 69% and 67%, respectively, of the month-to-date budget projections for January 2017.

45. Otezla net sales gained momentum in February. As of February 27, 2017, Otezla's month-to-date U.S. net revenue and unit sales were 88% and 84%, respectively, of the month-to-date budget projections for February 2017.

46. As of late March 2017, Otezla net revenue and unit sales were exceeding the budget projections for the month. As of March 20, 2017, Otezla's month-to-date U.S. net revenue and unit sales were 112% and 109%, respectively, of the month-to-date budget projections for March 2017.

47. Although Celgene reduced budget assumptions on or about March 24, 2017 regarding the anticipated growth in the PsO and PsA markets and Otezla's PsO and PsA market shares, Celgene importantly did not revise Otezla's overall 2017 net sales budget as a consequence and the revised assumptions still anticipated growth in the PsO and PsA market sizes and in Otezla's PsO and PsA market shares. Indeed, at this time, the view internally at Celgene was that (i) "FY Budget: OTEZLA net sales > $1.5B remains on track" and (ii) although "Otezla revenue forecast [for Q1 2017] is substantially below budget and consensus . . . [e]xecution on track [and] leading indicators . . . point to solid recovery in Q2-Q4 [2017]." Notwithstanding Otezla's strong March performance, Q1 2017 Otezla net sales fell short of the Q1 2017 budget, but the shortfall was less than 4% of Otezla's 2017 net revenue budget of $1.574B.

48. Recovering a significant portion of the Q1 2017 budget shortfall in later quarters in 2017 was viewed as a "realistic possibility" internally at Celgene in March 2017. However, Celgene did not need to recover any of the Q1 2017 Otezla budget shortfall in order to meet the 2017 guidance (projected net sales for Otezla totaled $1,272.2MM for Q2 through Q4 2017, which when added to the *actual* net sales of $242MM for Q1 2017, exceeds the guidance of $1,500MM for a projected total of $1,514MM ($1.574B – $60M = $1.514B)). If Otezla merely achieved the net sales budgets for the remaining quarters of 2017 without making up any of the Q1 2017 budget shortfall of approximately $60M, Otezla's net sales for the year would be $1.514B and within the guidance range $1.5B - $1.7B.

9. Otezla Net Sales in the First Three Weeks Of Q2 2017 Remained Strong

49. Otezla's strong March performance continued in April 2017. As of April 26, 2017, Otezla's month-to-date U.S. net revenue and unit sales were each 100% of the month-to-date budget projections for April 2017. Moreover, for the 12 weeks ending April 21, 2017, Otezla net

revenue increased from $89.1M for the first six weeks to $122.5M for the second six weeks, representing a "6-week over 6-week growth" in net revenue of 37.5%.

50. As of late April 2017, the view internally at Celgene remained that Otezla net sales were on track to the meet the 2017 full-year guidance.

10. Curran's Statement on the Q1 2017 Earnings Call Was Truthful and She Believed It

51. During the Q1 2017 earnings call ("Q1 2017 Earnings Call") that Celgene held on April 27, 2017, concerning its Q1 performance, Curran provided prepared remarks and responded to certain questions from analysts. This case concerns a cherry-picked statement Curran made during the Q&A portion of the Q1 2017 Earnings Call.

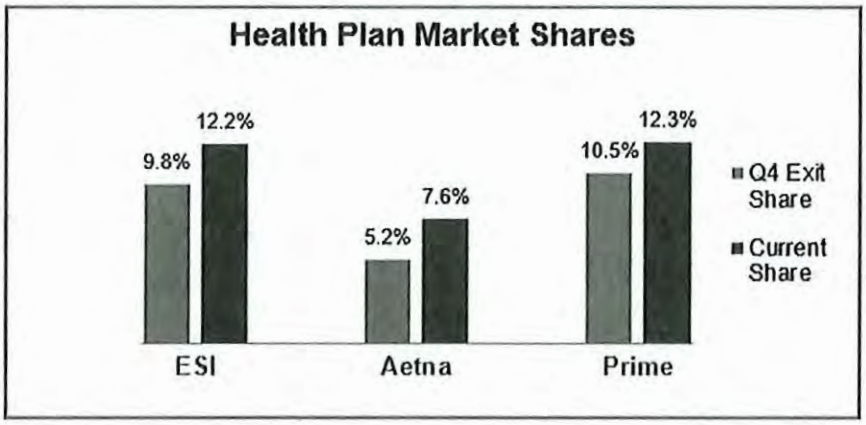
52. Specifically, during the Q&A portion of the Q1 2017 Earnings Call, a UBS analyst (Carter Gould) asked: "Can you just walk through what gives you confidence [Otezla] growth will bounce back or could we see continued pressure in the near term?" Curran responded truthfully as follows (the "April Statement"):

> Thank you, Carter. Yeah, I think you're spot on. I think there was really three key drivers to the performance in the first quarter. Firstly, we saw contraction in the market as we saw increased GTN [gross-to-net] as a result of the contracting, but importantly, that really gives us access to double the number of insured lives going forward. And lastly, we saw minimal drawdown of the inventory.
>
> Importantly, if we look at the underlying dynamics to the business, they're exceptionally strong. If you look at the market share, OTEZLA continues to grow market share. We continue to gain more than 40% of new patients and these new contracts will give us access to an additional pool of patients moving forward. Importantly, if we look at the exit run rates out of quarter one and into quarter two, we do see the net sales rebounding and on track to deliver the 2017 guidance.

53. Contrary to Plaintiff's assertion, no aspect of Curran's April Statement was false or misleading. The Court has already held that the April Statement was Curran's opinion. Curran honestly believed the April Statement was true and accurate at the time she provided it, the statement aligned with the information available to Curran at the time, and she had no intention to

deceive or mislead the market in any way at the time she made the April Statement. Indeed, she lacked any motive to do so.

54. Curran's comments that the "contracting . . . really gives us access to double the number of insured lives going forward" and that the "new entrants give Celgene access to an additional pool of patients moving forward" were accurate. The managed care contracts with ESI, Prime and Aetna increased Otezla's bio-step free access from approximately 30% of U.S. commercial lives in 2016 to approximately 58% in 2017. Moreover, shortly before the Q1 2017 Earnings Call, Curran was advised that, "[i]n terms of the key contracted health plans in the U.S. [ESI, Aetna, and Prime], market share gains have already been realized," as reflected in the following chart:



The "Current Shares" for each of the plans reflected in the chart "[a]chieved/exceeded target [market] shares for Q1."

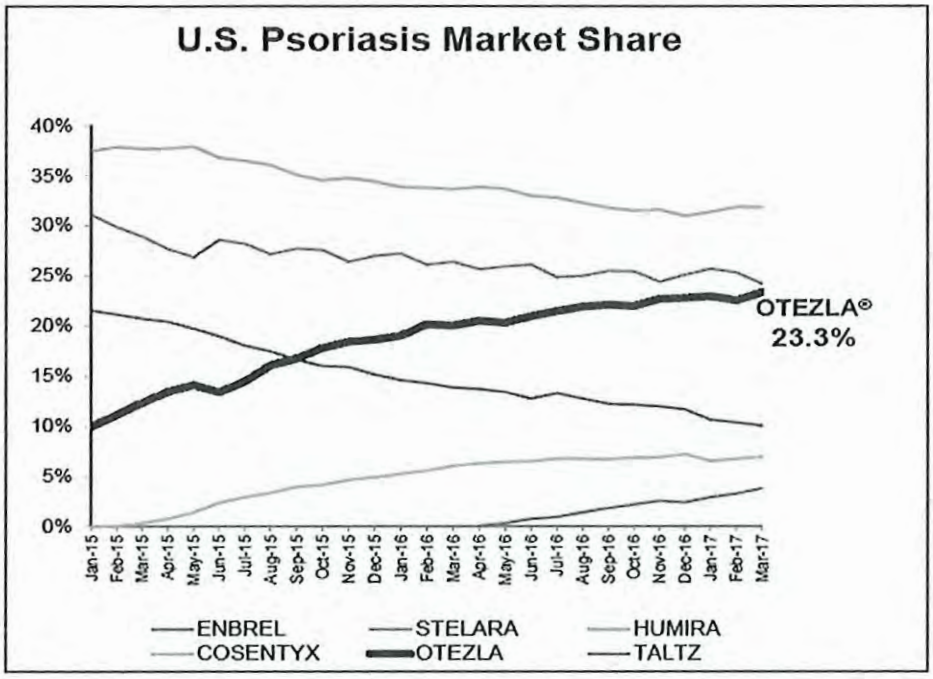
55. Curran's statement that one of the "three key drivers to [Otezla's] performance in the first quarter" was "minimal drawdown of the inventory" was consistent with the statement of Celgene's President and Chief Operating Officer, Scott Smith, earlier in the Q1 2017 Earnings Call that "a modest decline in inventory levels" contributed to Otezla's poor Q1 performance. It was also consistent with the slide that accompanied Smith's statement as well as with internal Celgene

documents. Moreover, as even Plaintiff concedes, Otezla's poor performance in Q1 2017 was attributable in part to the fact that, in December 2016, in anticipation of an Otezla price increase in January 2017, wholesalers accumulated "larger than normal" inventory levels of Otezla, which depressed Q1 2017 Otezla sales until the wholesalers drew down the excess inventories and resumed purchasing Otezla. This is precisely the problem Curran was talking about when she referred to a "minimal drawdown of the inventory." Indeed, Curran meant that wholesalers had not drawn down their "larger than normal" inventories enough in early Q1 2017 to cause them to have to restock, which depressed Q1 2017 Otezla sales.

56. Curran also specifically quantified the impact of the "minimal drawdown of the inventory" during the Q1 2017 Earnings Call. In response to an analyst's request to "provide a little bit more granularity as to what percent of the decline [in the Otezla net sales] was gross-to-net, what was [inventory] stocking, and what was the seasonality that you mentioned," Curran explained that "the total impact of inventory drawdown in quarter one was about $35 million to $40 million, but inventory levels exiting the quarter were at the low end of the normal range."

57. Curran's statement that she believed the "underlying dynamics" of Otezla's business were "exceptionally strong" was puffery and, in any event, consistent with internal Celgene documents and slides presented during the Q1 2017 Earnings Call. Among other things, internal Celgene documents indicated that "execution remains on track and leading indicators point to solid recovery in Q2-Q4 [2017]." (*Infra* ¶¶ 71-73.)

58. When Curran stated during the Q1 2017 Earnings Call that "Otezla continues to grow market share," she was referring to the following chart which was presented during the Q1 2017 Earnings Call and was publicly available to investors and analysts on Celgene's website:



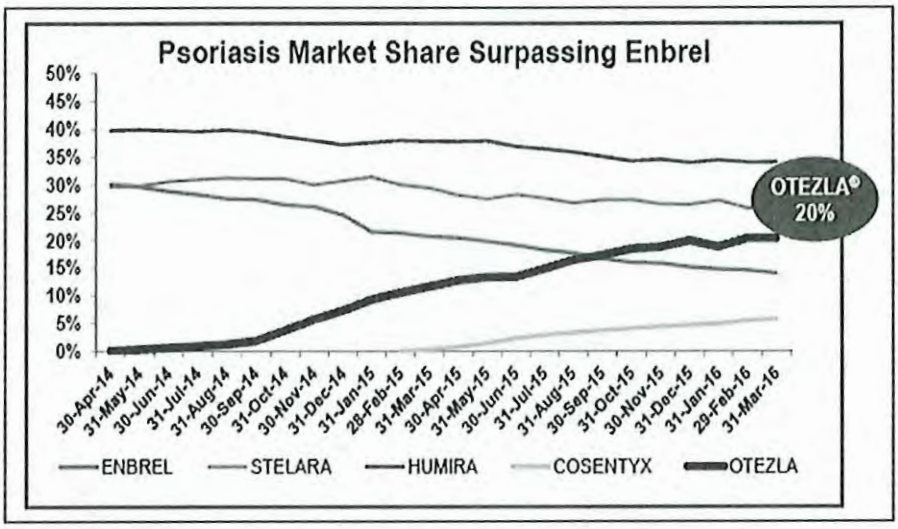
The presentation for which this chart was included had the following language:

> Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of factors, many of which are discussed in more detail in our Annual Report on Form 10-K and our other reports filed with the Securities and Exchange Commission.

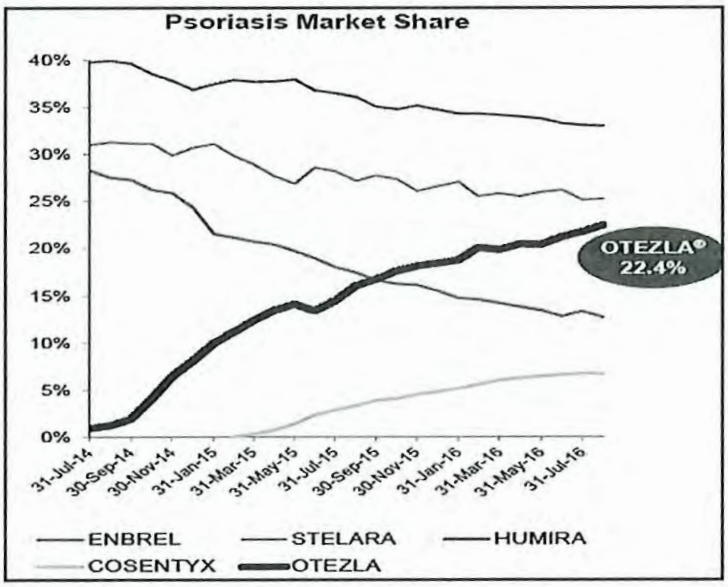
Moreover, this chart accurately depicted that Otezla's U.S. PsO market share increased from approximately 10% in January 2015 to 23.3% on March 31, 2017, within a six-drug market basket of branded drugs. The other branded drugs within the market basket, Enbrel, Cosentyx, Stelara, Humira and Taltz, were the main competitors that Celgene was focusing on strategically at the time.

59. The U.S. PsO market share chart to which Curran was referring during the Q1 2017 Earnings Call was the same type of chart Celgene had used in prior earnings calls to show the growth in Otezla's PsO market share:

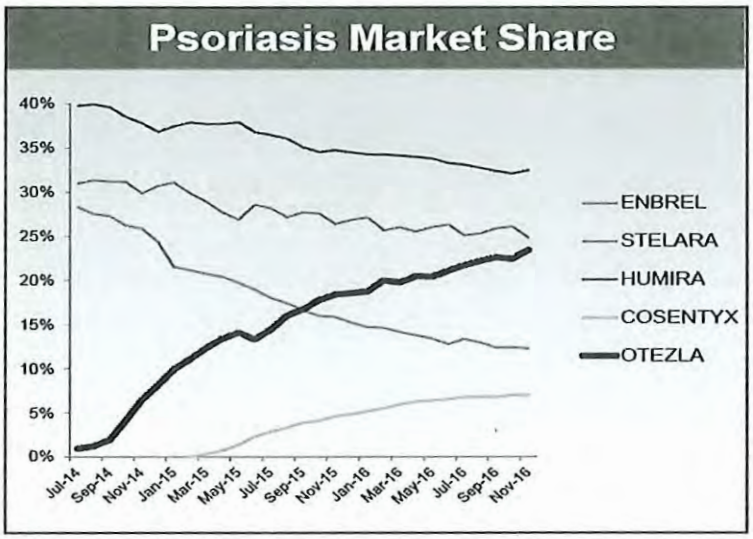
a. During Celgene's Q1 2016 earnings call on April 28, 2016, Celgene presented the following chart showing the growth in Otezla's PsO market share from April 30, 2014 to March 31, 2016, within a five-drug market basket of branded drugs:



b. During Celgene's Q3 2016 earnings call on October 27, 2016, Celgene presented the following chart showing the growth in Otezla's PsO market share from July 31, 2014 to July 31, 2016, within a five-drug market basket of branded drugs:

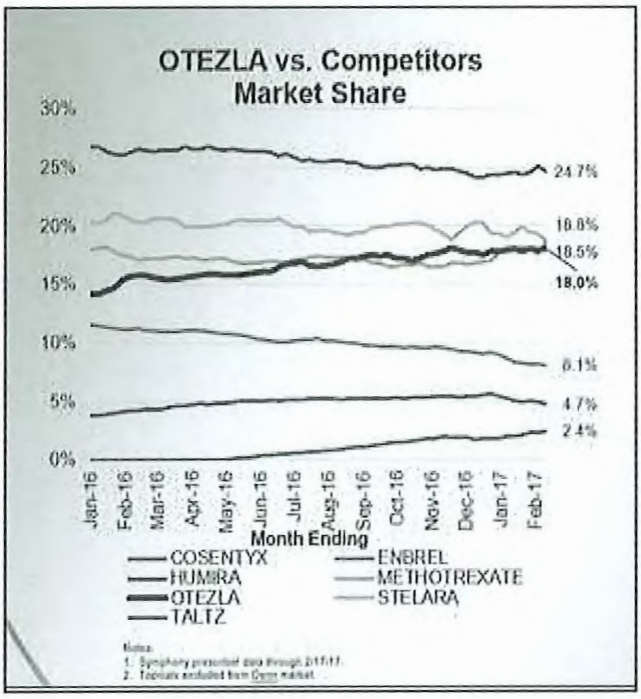


c. During Celgene's Q4 and full-year 2016 conference call on January 26, 2017, Celgene presented the following chart showing the growth in Otezla's PsO market share from July 2014 through November 2016, within a five-drug market basket of branded drugs:

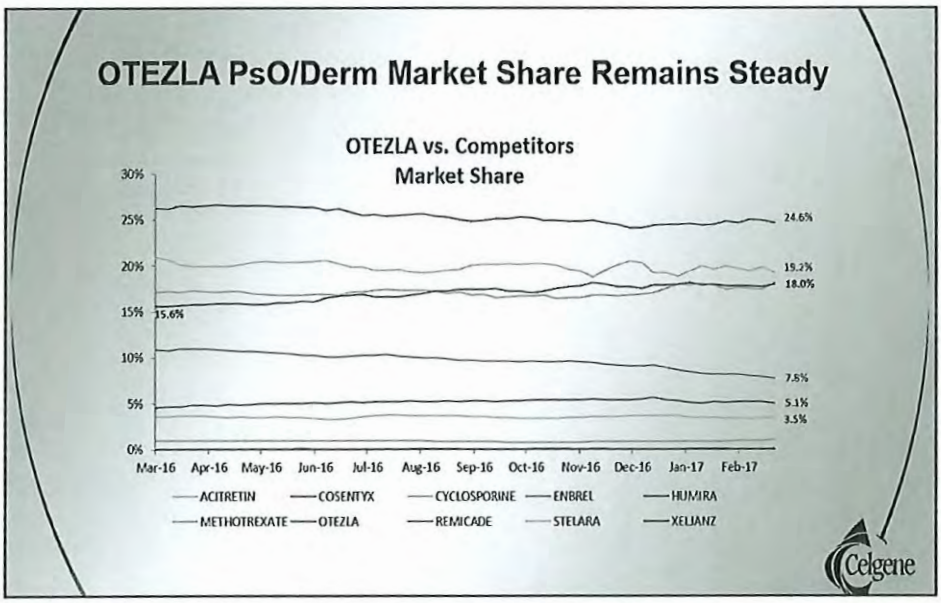


60. In addition, Curran's statement about market share was consistent with internal charts depicting Otezla's PsO market share growth over various periods of time within various market baskets of drugs:

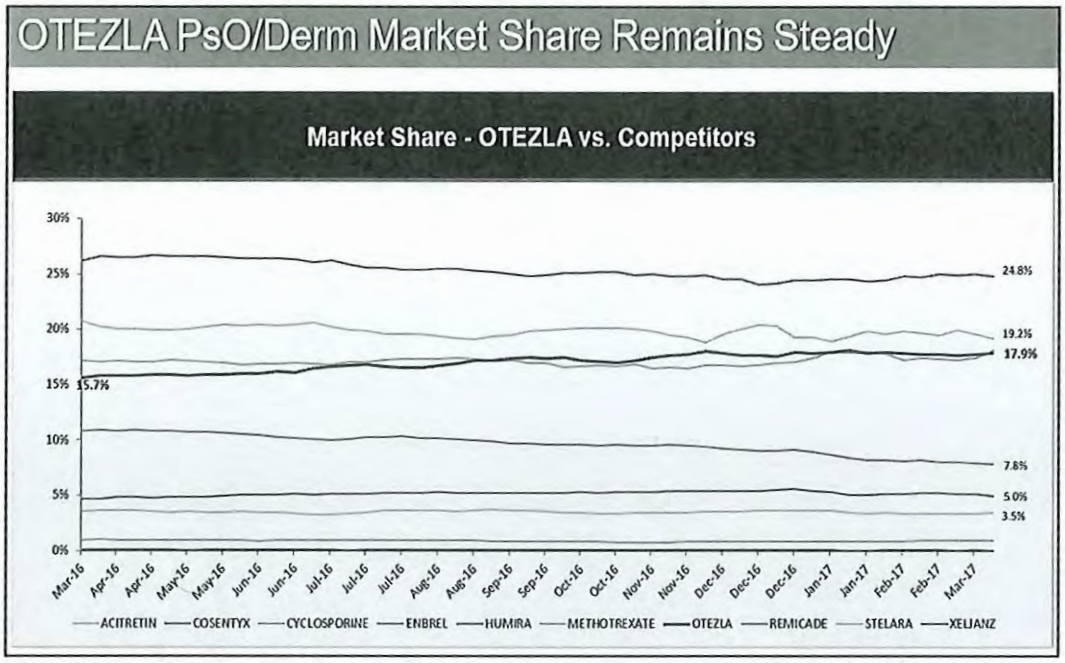
a. A chart contained in a March 9, 2017 presentation showed that Otezla's PsO market share increased from approximately 15% in January 2016 to 18% as of February 17, 2017, within a seven-drug market basket of six branded drugs and one generic drug:



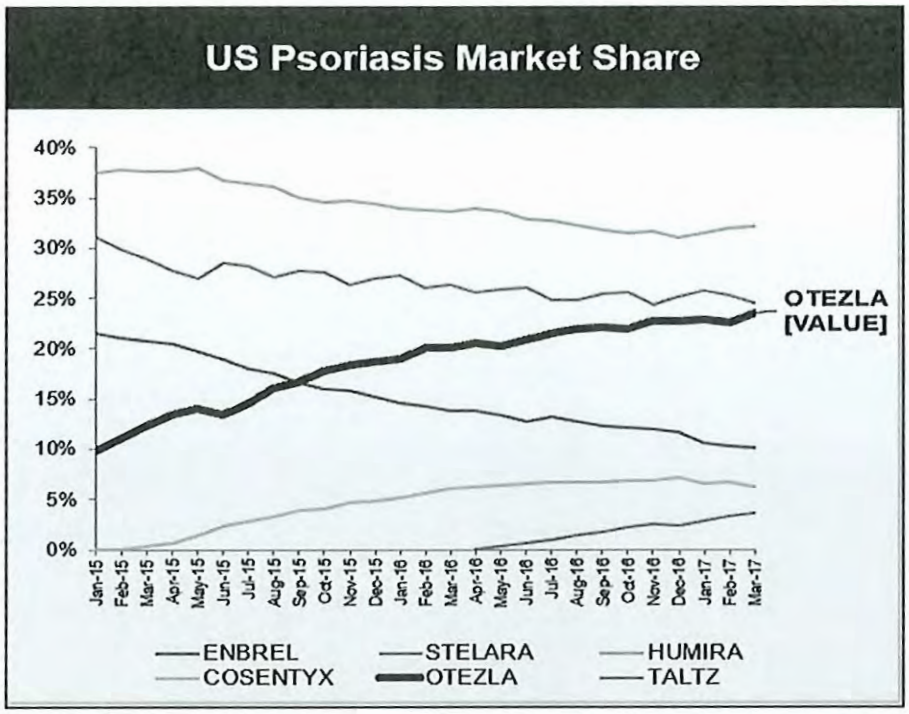
b. A chart contained in a March 27, 2017 presentation showed that Otezla's PsO market share increased from 15.6% in March 2016 to 18.0% as of March 10, 2017, within a ten-drug market basket of seven branded drugs and three generic drugs including methotrexate:



c. A chart contained in an April 10, 2017 presentation showed that Otezla's PsO market share increased from 15.7% in March 2016 to 17.9% as of March 17, 2017 within a ten-drug market basket of seven branded drugs and three generic drugs, including methotrexate:

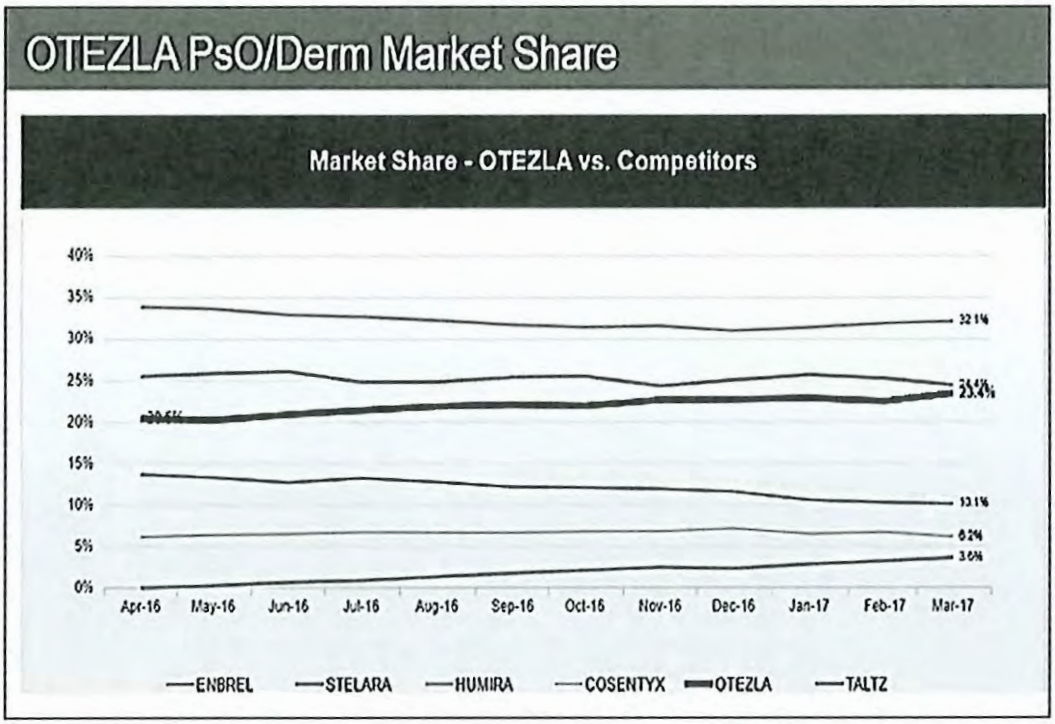


d. An April 18, 2017 presentation included the following chart showing that "Otezla's market share has continued to grow in the psoriasis market":



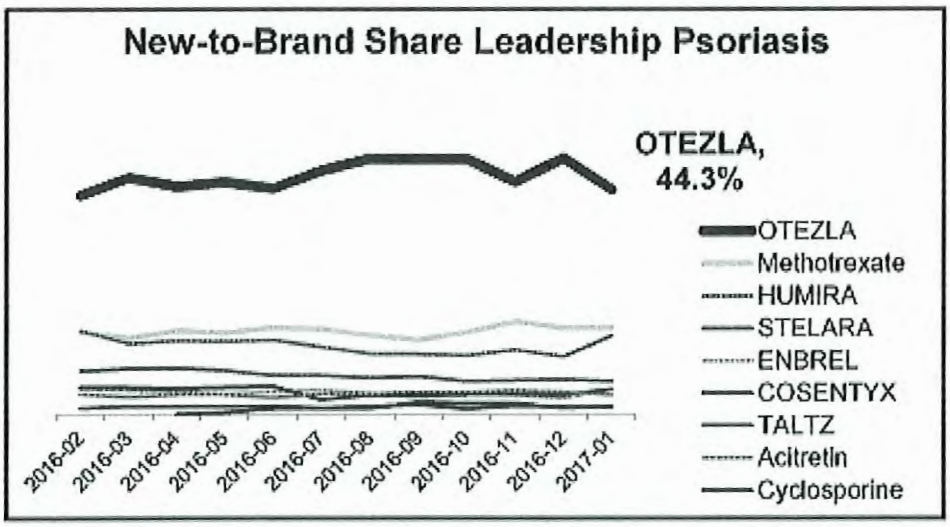
This chart closely resembles the one used during the Q1 2017 Earnings Call.

e. Another chart contained in a slide deck circulated on April 21, 2017 showed that Otezla's PsO market share increased from 20.5% in April 2016 to 23.4% as of March 31, 2017, within a six-drug market basket of branded drugs:



The data underlying this chart showed that Otezla market share increased in Q1 2017 from 22.7% to 23.4%.

61. Curran's statement during the Q1 2017 Earnings Call that Otezla was "gain[ing] more than 40% of new patients" was fully consistent with the following chart contained in a presentation she received shortly before the Q1 2017 Earnings Call:



This chart accurately depicted that Otezla's PsO new-to-brand share was 44.3% within a nine-drug market basket of six branded and two generic drugs, including methotrexate. Otezla's new-to-brand share represented its share of patients who were being prescribed a new drug for the first time. Celgene believed that new-to-brand share was a "good measure of product demand."

62. The Q1 2017 Earnings Call presentation, in which the above-referenced charts were included, contained the following cautionary language:

> Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of factors, many of which are discussed in more detail in our Annual Report on Form 10-K and our other reports filed with the Securities and Exchange Commission.

63. In turn, Celgene's Form 10-Ks and 10-Qs warned investors that "a revenue shortfall may cause financial results for a particular period to be below our expectations," among other things.

64. Curran's statement during the Q1 2017 Earnings Call that Otezla's "exit run rates out of quarter one and into quarter two" showed "net sales rebounding and on track to deliver the 2017 guidance" was consistent with information she received prior to the Q1 2017 Earnings Call:

a. While Otezla net revenues and unit sales underperformed relative to the budget in January and February 2017, recovery was noticeable in March and leading up to the Q1 2017 Earnings Call. Compared to the budget, Otezla's month-to-date US net revenue and unit sales performance increased from 69 percent and 67 percent respectively on January 23, 2017, to 88 percent and 84 percent respectively by the last week of February 2017, and to 112 percent and 109 percent respectively by March 20, 2017. Eventually, Otezla's US net revenue and unit sales exceeded its March budget projections. As of April 24, 2017 (*i.e.*, three days before the Q1 2017 Earnings Call), internal

presentations showed that Otezla's month-to-date US net revenue and unit sales were 100% of the quarter-to-date budget projections.

b. A March 27, 2017 deck indicated that (i) although "Otezla revenue forecast [for Q1 2017] is substantially below budget and consensus . . . [e]xecution on track and leading indicators (Rx, market shares, APLD [anonymous patient longitudinal data] point to solid recovery in Q2-Q4 [2017]" and (ii) "FY Budget: Otezla net sales > $1.5B remains on track."

c. An April 7, 2017 slide deck indicated that (i) although "Otezla revenue forecast [for Q1 2017] is substantially below budget and consensus . . . [e]xecution [is] on track and leading indicators . . . point to solid recovery in Q2-Q4 [2017]"; and (ii) "FY Budget: OTEZLA net sales > $1.5B remains on track."

d. An April 18, 2017 presentation indicated that Otezla was "On Track to Achieve US Q2 Forecast" and that there was "high confidence in achieving Q2 FCST."

e. An April 18, 2017 presentation similarly indicated that (i) notwithstanding Otezla's poor Q1 performance, 2017 global net sales were still forecast to be $1.57B (*i.e.*, within the guidance range of $1.5B - $1.7B); (ii) "execution remains on track and performance indicators point to accelerating trajectory in Q2-Q4 [2017]"; and (iii) the "[c]urrent run rate [is] consistent with Q2 [2017] forecast," with Otezla "[o]n track to achieve full year budget."

f. Curran received other presentations in March 2017 that were consistent with the April presentations described above.

g. On April 25, 2017, in preparation for Celgene's Q1 2017 Earnings Call, Curran specifically asked: "How do you go from the current run-rate to $1.5 to $1.7 billion

for the full year?" Celgene's Vice President of Finance and Celgene's Senior Director of Global Business Planning and Development responded that "[w]hile the quarter [Q1 2017] was below our internal expectations[,] we exited the quarter with strong performance and trends in March and April that are consistent with the run-rate necessary to meet the full year guidance." This is essentially what Curran said during the Q1 2017 Earnings Call.

11. Celgene Experienced Significant Sequential Growth for Otezla During Q2 2017 and Was on Track to Surpass $1.5B in Otezla Net Sales

65. Otezla net sales increased significantly in Q2: Otezla net sales in Q2 2017 were $358M, which was a 48% increase over Q1 2017 Otezla net sales of $242M.

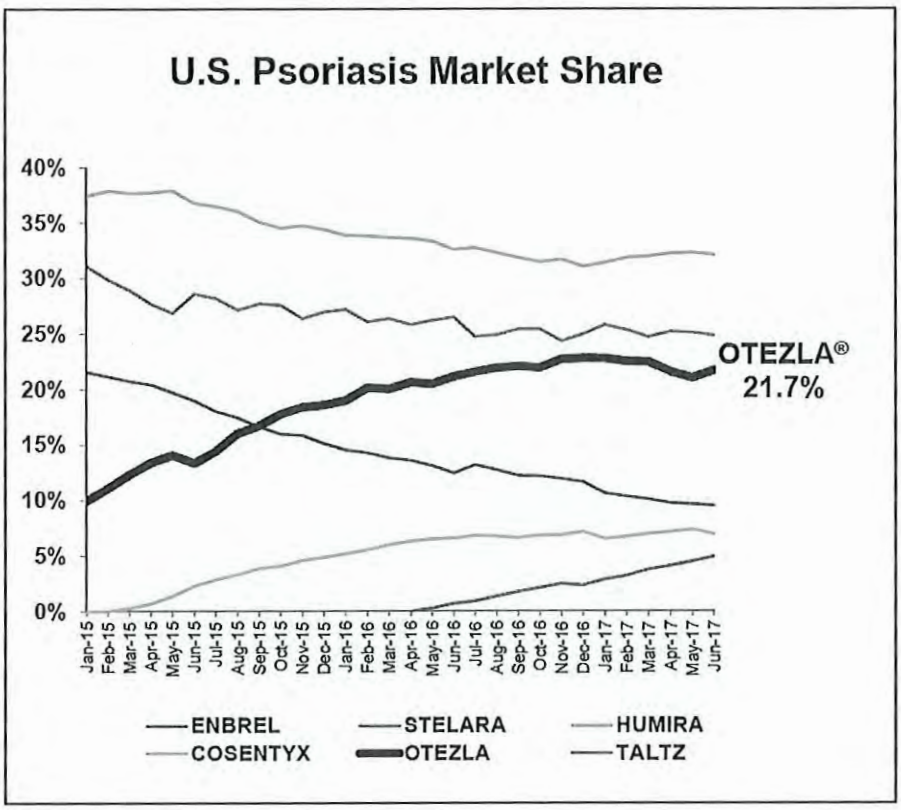
66. On July 27, 2017, during Celgene's Q2 earnings call ("the Q2 2017 Earnings Call"), Curran made the following truthful statement regarding Otezla (the "July Statement"):

> Q2 was an outstanding quarter for Celgene I&I, highlighted by significant sequential growth for OTEZLA. Key OTEZLA performance indicators continue to strengthen, and market share and prescriber adoption increased significantly in both U.S. and internationally. . . .

67. Curran believed the July Statement was true and accurate at the time she provided it. Her statement was accurate and supported by the information she received and relied on. Curran had no intention to deceive or mislead the market in any way at the time she made the July Statement.

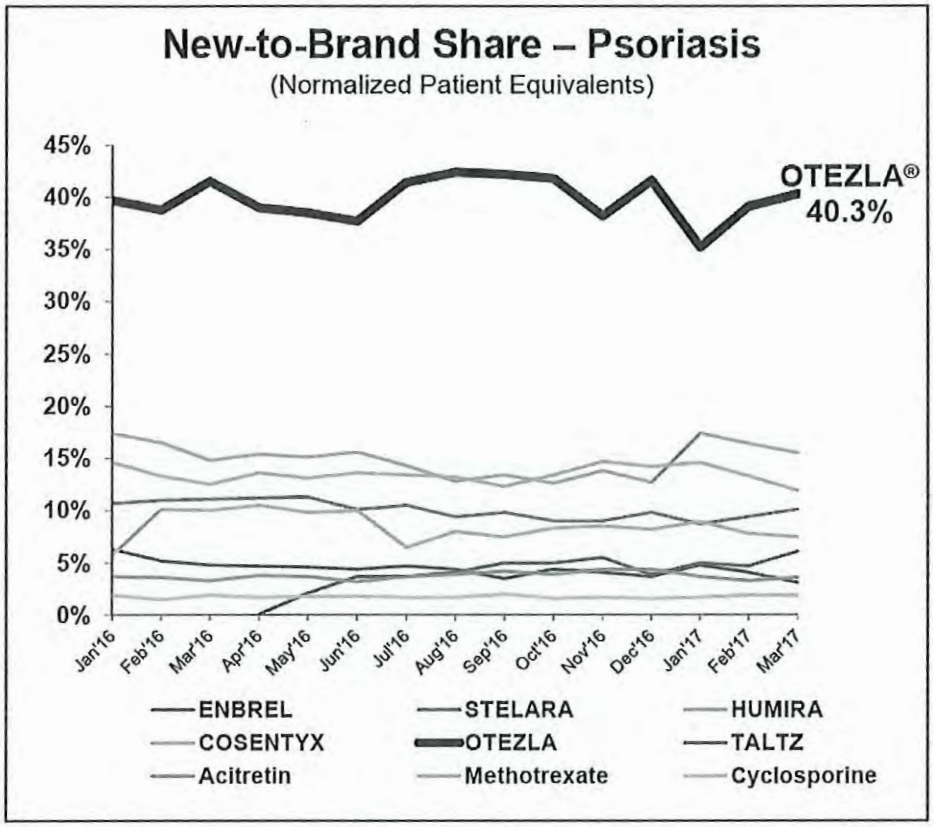
68. As Curran stated during the Q2 2017 Earnings Call, Otezla did in fact experience significant sequential growth in net sales in Q2 2017. Otezla net sales were $358M in Q2 2017, which was a 48% increase over Q1 2017 Otezla net sales of $242M.

69. When Curran commented about Otezla's market share during the Q2 2017 Earnings Call, she was referring to the following chart that was shown to participants while she was speaking:



This chart accurately depicted Otezla's U.S. PsO market share growth from approximately 10% in January 2015 to 21.7% as of June 30, 2017.

70. When Curran commented about "prescriber adoption" during the Q2 2017 Earnings Call she was referring to the following chart which was publicly available on Celgene's website:



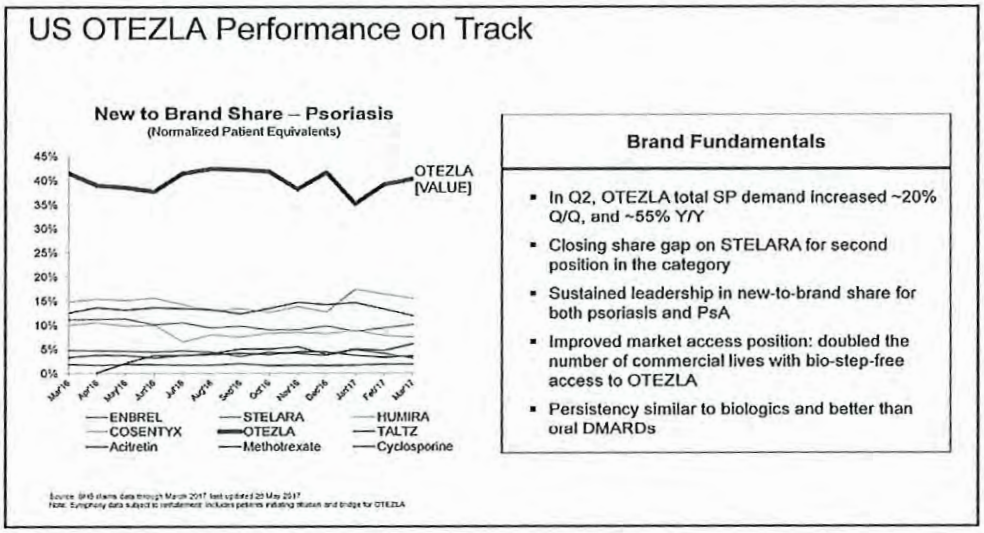
This chart accurately depicted that, as of June 30, 2017, Otezla's PsO new-to-brand share was 40.3% within a nine-drug market basket of branded and generic drugs, and Otezla led other drugs in PsO new-to-brand share by a significant margin throughout the period of January 2016 through March 2017. New-to-brand share was an important metric in predicting future market share for Otezla.

71. The Q2 2017 Earnings Call presentation, in which the above-referenced charts were included, contained the following cautionary language with a reference to the risk factors in Celgene's 10-Ks and other SEC filings:

> Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of factors, many of which are discussed in more detail in our Annual Report on Form 10-K and our other reports filed with the Securities and Exchange Commission.

72. In addition, shortly before the Q2 2017 Earnings Call, Curran was specifically informed that there was "[i]ncreasing [Otezla] adoption as U.S. and global access continues to improve."

73. Curran's statement that, "Key OTEZLA performance indicators continue to strengthen" was consistent with the information Curran was provided prior to the Q2 Earnings Call. Among other things, roughly a week before the Q2 2017 Earnings Call, Curran received a slide deck highlighting that Otezla was on track to surpass $1.5B in net sales for 2017. The slide deck also contained the following slide:



12. Celgene Updated Its 2017 Guidance Because Q3 Showed a Slowing of Growth in the PsO and PsA Markets and an Increase in GTN

74. In Q3 2017 in the U.S., there was a slowdown in the growth of the PsO and PsA markets, as well as an increase in GTN associated with the new managed care contracts. As a consequence, Otezla net sales fell short of the Q3 2017 budget.

75. On October 26, 2017, Celgene issued a press release reporting Q3 2017 financial results. In the press release, Celgene disclosed that Q3 2017 "OTEZLA® sales in the U.S. were impacted by an increase in gross-to-net adjustments from contracts implemented in January and a

slowing in overall category growth due to a more challenging market access environment." As a consequence, Celgene reduced Otezla's revenue guidance for 2017 from $1.5B–$1.7B to approximately $1.25B. The earnings press release on October 26, 2017 also updated the 2020 revenue guidance for the I&I division, which included Otezla, from over $4 billion to $2.6 billion – $2.8 billion (*i.e.*, the revenue guidance changed by $1.2 billion - $1.4 billion).

76. Also on October 26, 2017, Celgene held a Q3 2017 earnings call (the "Q3 2017 Earnings Call"), which was streamed online and also transcribed. During this call, Celgene reiterated why it was reducing the 2017 revenue guidance for Otezla (together, with the October 26, 2017 press release, the "October Disclosure"):

> Two major developments shaped the results of the third quarter and have impacted our short and longer-term outlook. First, while OTEZLA continues to maintain a strong U.S. market position, our 2017 forecast assumptions did not adequately anticipate the deep and persistent slowing growth of the psoriatic arthritis and psoriasis markets, especially during the entire third quarter. When combined with the discounts tied to the execution of our ongoing managed-care contracting strategy, we missed our third quarter OTEZLA sales target.

77. Curran further explained that "[i]n the past 2 years, the U.S. market for psoriasis and psoriatic arthritis grew strongly[,] . . . [w]e assumed that category growth rates would maintain these historical levels in setting our 2017 targets. However, year-to-date through September, both markets have experienced a significant slowdown in growth as a result of increasingly restrictive PBM formulary control." This explanation was accompanied by charts presented during the call showing significant reduction in the growth of both the PsO and PsA markets in 2017.

78. The October Disclosure did not correct Curran's April Statement, as it revealed nothing at all about Otezla inventory, PsO market share, exit run rates or rebounding sales out of Q1 into Q2, or whether Otezla sales were "on track" to meet guidance at the time of the April Statement.

79. Nor did the October Disclosure correct Curran's July Statement, as it revealed nothing about Otezla's Q2 performance, market share, or prescriber adoption.

80. Curran had no motive to mislead investors about Otezla's performance or prospects. Plaintiff does not allege she traded on inside information or that any part of her compensation or bonus was tied to whether Celgene was "on track" to deliver the guidance. Indeed, the only part of Curran's bonus related to Otezla sales concerned actual 2017 total net sales. Curran's statements about Otezla's performance along the way had no bearing on whether Celgene actually achieved those numbers.

13. In 2019, Amgen Purchased Otezla for $13.4 Billion

81. In January 2019, Bristol-Myers Squibb ("BMS") and Celgene announced a definitive merger agreement under which BMS would acquire Celgene. As a condition of the acquisition, the Federal Trade Commission required Celgene to divest Otezla.

82. Thereafter, Amgen Inc. ("Amgen") purchased Otezla from Celgene for $13.4 billion. Amgen viewed Otezla as a "strong strategic fit" that would provide Amgen "the unique opportunity . . . to provide patients an innovative oral therapy" for PsA and PsO. At the time of the announcement, Otezla was approved in 54 countries, including major markets such as France, Germany, and Japan. Since its launch in 2014, an estimated 840,000 patients have been treated globally with Otezla.

83. In November 2019, the acquisition was completed and Celgene became a wholly-owned subsidiary of BMS.

84. In 2020 and 2021, Otezla generated a total of $4.4B for Amgen.

B. Defendants Celgene and Martin intend to prove the following contested facts with regard to alleged liability for Ozanimod.

1. Ozanimod Background

1. At the time that Celgene acquired Receptos, Ozanimod was in Phase III clinical trials for the treatment of RMS, which were referred to as Sunbeam and Radiance, and for which there were thousands of enrolled patients. In connection with the submission of an NDA, FDA guidance instructs that two effective Phase III trials are needed.

2. Defendant Philippe Martin ("Martin") has over 20 years of experience in the pharmaceutical industry developing and commercializing medicines and has been involved in the submission of successful NDAs to the FDA.

3. As Managing Director of Celgene-Receptos, Martin's responsibilities included the development of Ozanimod. He did not report to anyone at the Receptos San Diego site. Martin reported directly to Curran.

4. Dr. Jean Louis Saillot ("Saillot") was one of Martin's direct reports and "the main person with whom [Martin] was interacting" on the Ozanimod NDA. Saillot "was leading the [Ozanimod NDA] submission."

5. The Ozanimod MS Team was a team of department leads responsible for the completion and submission of the Ozanimod NDA to the FDA. Beginning in 2016, Saillot led the Ozanimod MS Team which included Susan Meier-Davis ("Meier-Davis"), who was the nonclinical development lead, and Jonathan Tran ("Tran"), who was the clinical development lead. Martin, Scott Smith ("S. Smith"), Celgene's President and Chief Operating Officer ("COO"), and Curran were not members of the Ozanimod MS Team.

6. The Receptos Executive Committee, which was distinct from the IIEC, included Martin, Saillot, Tran, and Meier-Davis, among others. Curran and Smith were not on the Receptos Executive Committee.

7. As President of I&I, Curran oversaw the team responsible for the Ozanimod NDA. Curran was the only person from I&I that reported to S. Smith.

8. Curran did not always review Celgene's public disclosures, for example, Form 10-Ks were reviewed "at the executive committee level with Peter Kellogg [Celgene's Chief Financial Officer] and Mark Alles [Celgene's Chief Executive Officer]."

9. As President and COO, S. Smith was not responsible for overseeing the clinical development of, or regulatory matters involving Ozanimod. S. Smith was not a member of the IIEC, did not attend IIEC meetings, and did not receive most IIEC materials.

10. S. Smith was not involved in drafting any portion of Celgene's 10-Qs or 10-Ks. S. Smith's involvement with Celgene's 10-Qs and 10-Ks was limited to "reviewing any relevant sections and providing comments" if he had any. There was generally nothing for S. Smith to comment on, however, as the drafts he received were generally accurate. S. Smith's role with regard to Celgene's earnings press releases was similarly limited to reviewing drafts and providing comments if he had any. In advance of quarterly earnings calls, S. Smith would attend meetings along with "legal representation, investor relations" and "the people who were speaking" who "would generally write their own scripts." The general cadence of those meetings was to "talk about what the themes were, what are we going to talk about, what are the important things for investors and others to know from the prior quarter...." In addition, the group would "look at the slides, make a decision [ ] on what words should go in the slides and what should the general forum be."

11. A refusal to file ("RTF") is a regulatory decision from the FDA denying the complete review of an NDA.

2. Celgene Initiates a Mass Balance Study for Ozanimod

12. Metabolites are essentially the chemical byproducts of the body breaking down a drug. A radiolabeled mass balance study ("mass balance study") can test for the presence of metabolites in humans.

13. Celgene commenced the mass balance study once the radiolabeled material necessary to conduct the study was available.

14. In or around January 2017, Celgene received preliminary data from the mass balance study identifying a "peak" on the chromatograph, an instrument that enables the separation and testing of a drug's various components. These preliminary results necessitated further analysis to determine what the peak represented, such as a single metabolite, multiple metabolites, or something else entirely. Celgene began to assess what the potential discovery of a new metabolite might mean for its NDA submission.

3. Celgene Asks FDA About the Format and Presentation of the Data in Its Planned NDA

15. In December 2016, Celgene submitted an in-person meeting request to the FDA to discuss "plans for the format and presentation of data for a future NDA submission" as well as the sufficiency of Celgene's nonclinical and clinical pharmacology data.

16. On January 10, 2017, the FDA responded to Celgene and said in lieu of an in-person meeting, it would provide written responses to Celgene's questions. The FDA also told Celgene to wait to ask the agency questions concerning the sufficiency of Celgene's data until closer to the filing of its NDA.

17. On January 27, 2017, Celgene submitted a briefing book to the FDA, which contained Celgene's questions to the FDA concerning the format and presentation of its data in its planned NDA. A briefing book contains summary information for the FDA to consider in connection with an in-person meeting request or request for written feedback. In its January 27 briefing book, among other things, Celgene proposed submitting abbreviated study reports for certain of its ongoing studies. As Defendants' clinical pharmacology expert Dr. Sherry explains, abbreviated study reports are condensed versions of a full clinical study report ("CSR") that are generally used for studies not intended to support the efficacy and safety sections of an NDA.

18. On March 2, 2017, the FDA provided written responses to Celgene's January 27 briefing book. These responses addressed Celgene's proposal to submit several abbreviated study reports. Specially, the FDA stated, "[a]ccording to Table 3 of the submission, several phase l studies are still ongoing: RPC0I-1001, RPC0I-1902, RPC0l-1904, RPC0l-1905, RPC0I-1906, RPC0l-1907, RPC0I-1908 and RPC0I-1910. Full Clinical Study Reports are needed for these clinical pharmacology studies at the time of the NDA submission." S. Smith and Curran did not receive the FDA's written responses.

4. Celgene Reports Positive Results from Both Phase III Ozanimod Trials

19. On February 17, 2017, Celgene issued a press release which announced positive results from the Sunbeam Phase III trial for Ozanimod. The press release explained that the trial, which evaluated Ozanimod's safety and efficacy, showed that Ozanimod successfully reduced the relapse rate for patients with RMS.

20. On May 22, 2017, Celgene issued a press release announcing positive results from Radiance, the second Phase III trial for Ozanimod. The press release explained that the trial, which evaluated Ozanimod's safety and efficacy, showed that Ozanimod successfully reduced the relapse rate for patients with RMS.

5. Celgene Identifies the Metabolite

21. On June 22, 2017, through the mass balance study, Celgene confirmed RP112273 as a new Ozanimod metabolite (also referred to as CP112273, the "Metabolite"). The Metabolite was a disproportionate metabolite, which means "that is present only in humans or present at higher plasma concentrations in humans than in the animals used in nonclinical studies."

6. Background as to FDA Guidance Concerning Metabolites

22. The legal requirements for NDAs are contained in the Code of the Federal Register (the "CFR"). There are no legal requirements in the CFR for addressing metabolites in an NDA.

23. The FDA issues guidance, which are non-binding recommendations that represent the FDA's "current thinking" on an issue. The FDA's guidance explicitly states that they "do not establish legally enforceable responsibilities" and "and "do not operate to bind FDA or the public." The FDA permits drug sponsors to diverge from its guidance and develop alternative approaches, "if the approach[es] satisfies the requirements of the applicable statutes and regulations."

24. The FDA's Guidance on Safety Testing of Drug Metabolites ("MIST Guidance"), which was issued in February 2008, describes studies which "*may* need to be performed to assess the safety of the disproportionate drug metabolite." As Defendants' toxicology expert Dr. McGuinn explains, under the guidance, additional studies are not mandated, nor are they an appropriate response every time a disproportionate metabolite is discovered.

25. An "exposure multiple" refers to the ratio between metabolite exposure in humans as compared to animals. The MIST Guidance does not provide a threshold exposure multiple that needs to be achieved for disproportionate metabolites. Rather, the MIST Guidance recommends "levels comparable to those measured in humans." As Dr. McGuinn explains, this is intended to provide the FDA and drug sponsors with flexibility.

26. The FDA has also adopted as guidance the International Conference on Harmonization's ("ICH") "Guidance for Industry, M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals" ("ICH M3(R2) Guidance"), which was issued in 2010. The ICH M3(R2) Guidance provides the following recommendation for when characterization of disproportionate metabolites may be warranted:

> *Nonclinical characterization of a human metabolite(s) is only warranted when that metabolite(s) is observed at exposures greater than 10 percent of total drug-related exposure and at significantly greater levels in humans than the maximum exposure seen in the toxicity studies.*

27. Subsequently, in 2013, the ICH published a Q&A related to the ICH M3(R2) Guidance (the "ICH Q&A"), which was not guidance itself, but rather was intended to clarify issues raised by the ICH M3(R2) Guidance. The ICH Q&A provides:

> *Q1: In the M3(R2) guidance, what does "significantly greater" mean in the following statement: "Nonclinical characterization of a human metabolite(s) is only warranted when that metabolite(s) is observed at exposures greater than 10 percent of total drug-related exposure and at significantly greater levels in humans than the maximum exposure seen in the toxicity studies"?*
>
> *A1:... [C]haracterization of metabolite toxicity would generally be considered adequate when animal exposure is at least 50 percent the exposure seen in humans.* ***In some cases, for example when a metabolite composes the majority of the total human exposure, it is appropriate for exposure to the metabolite in animals to exceed that in humans.... In this latter case it is important to achieve a higher exposure to the metabolite in animals because this metabolite constitutes the bulk of human exposure.*** (emphasis added)

28. The ICH Q&A states that in some cases it may be "important to achieve a higher exposure to the metabolite in animals," but this is not mandated and is also not quantified. As Dr. McGuinn explains, it may not be possible to obtain large exposure multiples, particularly if a drug is sufficiently toxic to animals to preclude high doses.

7. Celgene Consults with Former High-Level FDA Officials About Its Plan to Address the Metabolite in the Ozanimod NDA

29. For purposes of pre-NDA submissions and discussions with the FDA, it was "typical" for Celgene to engage consultants that were formerly employed by the FDA "to give you a sense of where you stand and whether as ex-FDA reviewer[s] they would accept your submission and to try to understand whether they have any questions or anything you could add or change to your dossier that would make it better." As Meier-Davis explained, "[e]x-FDA people are extremely valuable to us working in the pharmaceutical industry, because they have seen a lot of different submissions and can often help to problem solve."

30. After identifying the Metabolite, Celgene retained consultants Dr. Lawrence Lesko ("Lesko"), Dr. Russell Katz ("Katz"), and Dr. David Jacobson-Kram ("Jacobson-Kram," and collectively with Lesko and Katz, the "FDA Consultants").

31. Lesko was at the FDA for 20 years. In 1995, he was appointed Director of the FDA's Office of Clinical Pharmacology, a position he held until July 2011.

32. Katz was the former Director of the Division of Neurology Products in the Office of New Drugs ("OND"), Center for Drug Evaluation and Research at the FDA from 1999 until he retired in June 2013. Celgene was submitting the Ozanimod NDA to this very Division, given it was a neurology product.

33. Jacobson-Kram was employed at the FDA from 2003 through 2014. He was the Associate Director of Pharmacology and Toxicology at the OND in the Center for Drug Evaluation and Research at the FDA. In this role, he was the lead pharmacologist and toxicologist at the FDA. While at the FDA, Jacobson-Kram was also the Chairman of the FDA's Executive Carcinogenic Assessment Committee. He also served as the primary head for toxicology issues for the ICH throughout his tenure at the FDA.

34. The respective offices and division that formerly employed the FDA Consultants at the FDA would review Celgene's Ozanimod NDA.

35. Celgene had developed a plan to address the Metabolite in the Ozanimod NDA that it wanted to discuss with the FDA Consultants. Celgene's plan included providing the FDA with additional long-term stability ("LTS") data for the Metabolite during the NDA review period, *i.e.*, at the 120-day safety update. Providing supplemental information to the FDA during an NDA review period is common. As Martin testified, the strategy "to provide additional data during an FDA review is something that is often done during an NDA submission." Similarly, Saillot testified that it was "very common to provide a certain amount of data" to the FDA "and then complement the data as the data becomes available," including with "analytical stability" and "product stability" data like the LTS data Celgene intended to supplement. Moreover, as Dr. Sherry explains, there are no legal requirements for LTS data in an NDA and the FDA's Guidance for Industry, Bioanalytical Method Validation Guidance ("BMV Guidance"), which addresses LTS, does not state when LTS data should be provided to the FDA nor that LTS data must be included in an NDA. The BMV Guidance also does not state that all pharmacokinetic samples in a study need to be analyzed.

36. In addition, Celgene's plan to address the Metabolite included relying on its previously conducted pivotal toxicology studies to characterize the Metabolite. Pivotal toxicology studies include general toxicology studies, genotoxicity studies, carcinogenicity studies, and embryo-fetal development toxicology studies.

37. On July 20, 2017, Celgene hosted a meeting with the FDA Consultants. The purpose of the meeting was to review the Metabolite "data and plans," finalize questions to pose to the FDA, obtain "[i]nput on proposed activities to be conducted and [the] timing of providing

those to FDA" in the NDA and during the FDA review period, and obtain an "expert opinion on Celgene's strategy to characterize Clinical Pharmacology properties of [the Metabolite] in support of [the] NDA submission."

38. Martin believed the meeting with the FDA Consultants was "important" because "[w]e wanted to make sure that the ex-FDA reviewer[s] would give us a sense as to whether our submission would be accepted and whether we would get approval based on what the team had put together and based on the plan that had been put together by Celgene subject matter experts." Martin attended the meeting with the FDA Consultants because he "wanted to hear how the ex-FDA consultants felt about our submission and whether they had any objections to the submission."

39. At the meeting with the FDA Consultants, Celgene presented two slide decks. The information presented included a summary of the available clinical pharmacology data for Ozanimod at the time of the anticipated NDA submission in December 2017, and the additional data that would be subsequently made available to the FDA during its review of the Ozanimod NDA in 2018. One of the slides presented stated there would be no LTS data for the Metabolite at the time of the NDA submission. And another slide explicitly asked: "[a]s a former FDA reviewer[] how would you react to the late identification of a major active metabolite and a Sponsor's proposal to submit partial information initially with additional data provided during the review?" Lesko confirmed that these particular slides were shown at the meeting.

40. Lesko believed that Celgene's plan to supplement the NDA with additional information during the FDA's review was reasonable, and he was not concerned about Celgene receiving an RTF from the FDA in connection with the submission of the Ozanimod NDA. As Lesko testified, "[m]ost of the clin pharm packages in NDAs are incomplete. It's rare to find a

perfect application. And generally for clin pharm it's unusual to have an RTF. Usually for clinical pharmacology the absence or uncertainty [of] information is handled by labeling and by a post-marketing commitment."

41. At the meeting, Celgene also presented slides to the FDA Consultants with its exposure multiple data for the Metabolite in each of its pivotal toxicology studies. In addition, Celgene presented exposure multiple data using a summed approach for total active agonist ("Total Agonist") that was similar to a summing approach used with the drug Ivacaftor for exposure multiples. Tran identified Ivacaftor as a drug with disproportionate metabolites that the FDA approved with a 0.8 exposure multiple.

42. At the meeting, Celgene asked the FDA Consultants if: (1) there were "gaps from the nonclinical perspective that we should consider," (2) "[g]iven the estimated safety multiples, we believe that [the Metabolite] is qualified. Do you concur?," and (3) is the "total agonist a valid index to calculate safety margins?"

43. The FDA Consultants did not tell Celgene that it would need to conduct any additional nonclinical studies in order to characterize the Metabolite.

44. None of the FDA Consultants told Celgene that an RTF was likely. As Martin testified, an RTF was "certainly not something [the FDA Consultants] believed was a possibility." During the meeting, Celgene had asked Lesko if there were any potential concerns that the FDA would not accept the stability data they had at the time of submission, and "[Lesko's] feedback was that no, it's not likely, because you have strong efficacy data." Jacobson-Kram "didn't tell Celgene at any point," that he thought Celgene would get an RTF.

45. Martin recalls "all three consultants being very supportive of what the team was proposing and believed that the submission should be approved based on the data [that] will be

provided." According to Saillot, the FDA Consultants' message was that Celgene's approach was reasonable. Tran testified that the FDA Consultants felt the plan to supplement the NDA with LTS data during the FDA's review period was adequate and would be acceptable to the FDA.

8. Curran and S. Smith Are Informed About the Metabolite, Which Was Not Expected to Impact Approvability of the NDA

46. On July 25, 2017, Curran and S. Smith first learned of the discovery of the Metabolite. Specifically, on that date, Martin sent an email to Curran, which stated in part:

> A recently completed human mass balance study revealed a new disproportionate metabolite RP112273 which was not previously detected in preclinical species. The good news is that the team here has been able to do a lot of work in a very short timeframe to better understand the situation and potential implications. Preliminary data indicates that our story remains intact and that approvability is not impacted by this new finding. All the activities that could be done to qualify RP112273 have been conducted or are on-going, and recent feedback from ex-FDA reviewers (tox, clin pharm and division director level) indicates that our plan/data should be acceptable to the agency and allow us to keep the submission on schedule.

Martin also provided further details about the Metabolite and planned next steps. The same day, Martin forwarded this email to S. Smith.

9. Celgene Continues to Engage with Consultants Following the July 20 Meeting

47. Celgene continued to engage with its consultants as it prepared for the Ozanimod NDA submission. On August 1, 2017 Meier-Davis provided Jacobson-Kram with exposure multiples for each of its pivotal toxicology studies and asked him if the exposure multiples were "adequate" under the ICH Q&A. Jacobson-Kram responded "I think your initial position should be that you have sufficient coverage [for the]... metabolite and that additional studies are not warranted."

48. In August 2017, Celgene retained another former FDA non-clinical reviewer to consult on the Ozanimod NDA, Dr. Marcie Wood ("Wood"), who had experience reviewing

neurology submissions while she was at the FDA. Wood never suggested to Celgene that it would need to conduct additional nonclinical studies as a result of the Metabolite.

49. On August 2, 2017, Wood told Meier-Davis that "an exposure multiple should not be calculated for the transgenic [6-month mouse] study, since FDA doesn't include exposure multiples for transgenic studies in product labeling." Moreover, as Dr. McGuinn explains, Celgene's 6-month mouse study found that Ozanimod causes cancer in mice and a different exposure to the Metabolite in this study would not change this finding. From a regulatory perspective, once the 6-month mouse study demonstrated a positive result for cancer, the carcinogenic potential of the drug had been adequately characterized.

50. Similarly, Dr. McGuinn will explain that there was no need for higher exposure to the Metabolite in Celgene's rabbit embryo-fetal development study because the study demonstrated that Ozanimod was an embryo-fetal toxin.

51. On August 14, 2017, Martin responded to the July 25 email he sent to Curran and told Curran that "[t]he same bullet points that I originally sent you still apply."

52. On August 16, 2017, Meier-Davis emailed Wood updated exposure multiple data for the rat carcinogenicity study and asked for her thoughts on the 0.8 multiple. Wood responded that "the 0.8 multiple should be adequate for characterizing the carcinogenic potential of your drug" and that the Total Agonist approach was not necessary.

53. The FDA encourages applicants to schedule a "Pre-NDA Meeting" in advance of submitting an NDA, in order to facilitate "exchanges of information about" the submission. Accordingly, before submitting the Ozanimod NDA, Celgene requested a pre-NDA meeting with the FDA, which was granted and scheduled for November 28, 2017 ("the "pre-NDA Meeting"). Celgene was required to submit a briefing book ahead of the pre-NDA Meeting ("the pre-NDA

Briefing Book") containing "(i) [a] brief summary of the clinical studies to be submitted in the application, (ii) [a] proposed format for organizing the submission, including methods for presenting the data, (iii) [i]nformation on the status of needed or ongoing pediatric studies, [and] (iv) [a]ny other information for discussion at the meeting."

54. On August 22, 2017, Meier-Davis sent Jacobson-Kram draft sections of the pre-NDA Briefing Book, which included the latest exposure data for the Metabolite. Jacobson-Kram responded, "I think the briefing book makes as good an argument as can be made" in light of the discovery of the Metabolite late in development. Although Jacobson-Kram stated that the FDA could require Celgene to demonstrate higher exposures, this was only in the unlikely event that the FDA considered Ozanimod to be a prodrug, which is an inactive drug that metabolizes into an active drug after ingestion. Jacobson-Kram testified that Ozanimod was not a prodrug. The FDA never considered Ozanimod to be a prodrug.

55. On October 16, 2017, Maria Palmisano ("Palmisano"), Celgene's Corporate Vice President for Clinical Pharmacology and the internal subject matter expert on clinical pharmacology, was sent a draft of Celgene's pre-NDA Briefing Book for review. Palmisano complimented the clinical pharmacology section of the draft pre-NDA Briefing Book, which was relayed to Martin.

56. On October 19, 2017, Matthew Lamb ("Lamb"), Celgene's Vice President and Global Head of Regulatory Affairs for I&I, sent Florence Houn ("Houn"), Celgene's Vice President of Global Regulatory Science, a copy of the draft pre-NDA Briefing Book. Houn was not part of the Ozanimod MS team and had no involvement with the Ozanimod NDA previously. Houn only spent a few hours reviewing the 129-page pre-NDA Briefing Book after which she sent

comments to make the pre-NDA Briefing Book easier to "digest." Houn only interacted with Lamb on the Ozanimod NDA and did not send her comments to anyone else.

57. On October 20, 2017, Lamb sent Curran a copy of the draft pre-NDA Briefing Book with his comments and stated that the Ozanimod team was working to "address the critical points." One of Lamb's comments in the draft pre-NDA Briefing Book stated that his "first impression" was to "wait" until certain CSRs were available. That comment, however, concerned a section of the draft pre-NDA Briefing Book unrelated to LTS data.

10. The October 26 Statements

58. Between July 25, 2017 when Curran was first informed of the Metabolite and October 2017, Curran did not receive any information contradicting Martin's assurance that "approvability is not impacted by [the Metabolite]" and that "recent feedback from ex-FDA reviewers (tox, clin pharm and division director level) indicates that our plan/data should be acceptable to the agency and allow us to keep the submission on schedule."

59. On October 26, 2017, Celgene filed a Form 10-Q signed by Alles and Kellogg, which accurately stated "we have phase III trials underway for ozanimod in relapsing multiple sclerosis." Celgene also issued a press release that stated that "Celgene plans to submit a New Drug Application (NDA) to the FDA for ozanimod in RMS by year-end."

60. The October 26, 2017 press release contained the following cautionary language:

> Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of factors, many of which are discussed in more detail in our Annual Report on Form 10-K and our other reports filed with the Securities and Exchange Commission.

61. In turn, Celgene's Form 10-Ks and 10-Qs—including the 10-Q filed on October 26, 2017—warned investors that "preclinical tests and clinical trials can take many years . . . and the data obtained from these tests and trials may not lead to regulatory approval" and that "[d]elays or

rejections may be encountered during any stage of the regulatory process if the clinical or other data fails to demonstrate compliance with a regulatory agency's requirements for safety, efficacy and quality."

62. On the same date, during Celgene's Q3 2017 earnings call slides were presented which accurately stated that Ozanimod was "[m]oving [f]orward in Multiple Sclerosis," and that the company was "preparing for regulatory submission to the FDA by year-end." Another slide noted "2017 Inflection Points with Multiple Value Drivers Delivering," and "Ozanimod FDA filing in RMS by YE:17."

63. The earnings call slides contained the same cautionary language as in the press release issued on the same day, with the same reference to the risk factors in Celgene's 10-Ks and other SEC filings.

11. Celgene Submits its Pre-NDA Briefing Book to FDA

64. On October 27, 2017, Celgene submitted its pre-NDA Briefing Book to the FDA. In its pre-NDA Briefing Book, Celgene presented the plan it had vetted with the FDA Consultants for addressing the Metabolite in the NDA, including providing limited LTS data at the time of submission and supplementing that data during the review period and relying on previously conducted pivotal toxicology studies to characterize the Metabolite. Celgene sought confirmation from the FDA that this plan was acceptable.

65. Consistent with Celgene's view that its nonclinical package would be sufficient as to the Metabolite, it did not seek any extensions nor permission to supplement its nonclinical data in its pre-NDA Briefing Book.

12. Martin Speaks at ECTRIMS

66. Between the July 20, 2017 meeting with the FDA Consultants and October 2017, Martin did not receive any documents, opinions, or other information calling into doubt the

anticipated success of the plan blessed by the FDA Consultants. Indeed, Martin was not aware of "any Celgene employee or consultant stating or expressing the view that the ozanimod NDA should not be submitted in December of 2017." Nor did he recall "any employee or consultant stating that an RTF was 'likely' with regard to the Ozanimod NDA." To the contrary, the Ozanimod team remained confident in this plan. For example, Meier-Davis told Martin that "the NDA from a nonclinical perspective is in good shape."

67. On October 20, 2017, in preparation for an earnings call and conference, Martin forwarded to Saillot and others an Ozanimod program timeline slide indicating that the Ozanimod NDA was going to be filed at the end of 2017 and asked them to "[p]lease look at the slide and let me know if anything should be changed." No one proposed changing the date for the filing of the Ozanimod NDA.

68. On October 28, 2017, at the MSParis2017-7th Joint American-European Committee for Treatment and Research in Multiple Sclerosis ("ECTRIMS"), Martin stated truthfully, "the RADIANCE study and the SUNBEAM study will form the basis of our submission to the FDA and to EMA [European Medicines Agency]. For the FDA, we are working hard as we speak to get ready to file by the end of the year and early next year for EMA."

69. Martin believes that the statements he made about Ozanimod on October 28, 2017 were true and accurate at the time he made them.

70. Martin did not mention the Metabolite in his statements about Ozanimod on October 28, 2017 because he believed "the metabolite had no impact either on the quality of the data and robustness of the data … and had no impact on the timing for the NDA." Martin believed that because "we had worked with the team and the various experts that we had engaged including ex-FDA reviewers that all believed that our package looked good, was reasonable, and the plan

was reasonable, and that we should not – we would not get a Refusal-To-File and that this drug should be eventually approved."

71. Martin's October 28, 2017 statement was accompanied by a slide deck. The slide deck included the following cautionary language, which referenced the risk factors in Celgene's 10-Ks and other SEC filings:

> Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of factors, many of which are discussed in more detail in our Annual Report on Form 10-K and our other reports filed with the Securities and Exchange Commission.

72. Scott Smith began the October 28, 2017 presentation in which Martin made the above statement by stating, "[w]e're going to be obviously talking about events in the future."

13. Celgene Continues to Engage with Consultants in Preparation for NDA Submission

73. On November 2, 2017, in preparation for the pre-NDA Meeting, Meier-Davis provided the pre-NDA Briefing Book to Jacobson-Kram. Jacobson-Kram responded with questions for Celgene to consider involving "issues one might expect FDA to raise" at the pre-NDA Meeting. Jacobson-Kram explained that by "issues" he did not mean concerns about an RTF. In drafting the questions, Jacobson-Kram "was trying to put [him]self in the position of a very conservative reviewer and trying to come up with the most difficult questions [he] could in anticipation of Celgene's meeting with the FDA."

74. In November 2017, Celgene consulted yet another external toxicologist, Dr. James MacDonald ("MacDonald"). MacDonald did not have prior experience working at the FDA. In connection with his consultation on the Ozanimod NDA, MacDonald never had the risk of an RTF in mind. Indeed, MacDonald told Celgene that they "had a uniquely effective molecule in a tough to control disease" and testified that "there [was] nothing in the package that [he] saw that suggested risk." He further testified that Celgene could assert the "drug is not going to pose a risk

to humans." MacDonald never told Celgene it needed to conduct additional nonclinical studies in order for its NDA to be accepted.

75. On November 19, 2017, Lamb emailed Curran and others that Celgene had the opportunity to purchase a Priority Review Voucher ("PRV"), which could expedite the FDA's review of the Ozanimod NDA. Lamb contemplated that the FDA could agree with Celgene's proposal in its Briefing Book, in which case a PRV would be unnecessary. If the FDA made a recommendation that Celgene should wait to submit the NDA until early 2018, then Lamb suggested the PRV might make sense. Celgene did not pursue a PRV for the Ozanimod NDA.

14. The FDA Provides Comments to the Briefing Book, Which Gave Celgene the Information It Needed to Finalize the NDA

76. On November 21, 2017, almost one month after Martin's statement at ECTRIMS, Celgene received written responses from the FDA to the questions presented in its pre-NDA Briefing Book (the "FDA's Comments").

77. In response to Celgene's Question 3, which asked, "[d]oes the Agency agree that the proposed nonclinical package, including the evaluation of major metabolites, is adequate to support the filing for the registration of ozanimod?", the FDA stated, "[t]he adequacy of the data will be a matter of review."

78. As Dr. McGuinn explains, had the FDA intended to communicate that Celgene's data was insufficient, they would have said 'no' in response to Celgene's question or would have explicitly informed Celgene that it needed to rerun certain studies. The FDA's response that "[t]he adequacy of the data will be a matter of review" meant that following the FDA's filing of the NDA, and during review of the accepted NDA, the FDA would determine if the NDA contained enough data. In other words, it was an indication that the NDA would proceed past the RTF stage, wherein the FDA would accept the filing, and then evaluate it further. As Saillot testified, "basically

everyone read this question three as... they're fine with what we have, they're going to review it... But what we are providing for their review is adequate." Similarly, Martin testified that "matter of review [is] post acceptance [by] the FDA. So this is a review issue as we call them.... During the review the FDA will determine if you have enough data to give you approval for the drug."

79. In response to Question 5, which asked, "[d]oes the Agency agree with Celgene's proposed timing for the bioanalytical data package for the recently-identified major active metabolite RP112273?", the FDA stated, "[i]f [Celgene] used retained plasma samples to quantify RP112273 in the relevant Phase 1 studies, [Celgene] will need to provide evidence that demonstrates the stability of RP112273 in human plasma at the time of the NDA submission."

80. As Tran testified, the FDA Comments did not "say that [Celgene] needed to provide stability data for all the samples or [ ] how long [Celgene] need[ed] to provide" LTS for. Nor did the FDA state that Celgene would receive an RTF if the requested LTS data was not provided. As Dr. Jay Backstrom ("Backstrom"), Celgene's Chief Medical Officer explained, "[i]f [FDA] disagrees [with a sponsor's strategy], they're usually clear in telling you that. Their answer would be, "No, you need to do something else."

81. In response to Question 4, a different question which did not concern LTS data, but asked whether the FDA would be willing to accept an abbreviated, instead of a full, clinical study report, the FDA responded "[n]o" and commented, "[y]ou propose to submit an abbreviated CSR of study RPC01-1001 at the time of the NDA submission," but a "full" CSR is needed for this study.

82. On November 22, 2017, Celgene asked for clarification from the FDA as to whether it could submit the "full CSR for Study RPC01-1001 within 1 month after the NDA submission...."

The FDA responded that the full CSR for RPC01-1001 was expected to be included in the original NDA submission.

83. In advance of the pre-NDA Meeting, the Celgene project team determined they had all the information that they needed from the FDA and that they should focus on completing the work that still needed to be done on the NDA, including completing the CSR for RPC01-1001. Accordingly, they canceled the scheduled pre-NDA Meeting. Jacobson-Kram explained that it is common for pre-NDA meetings to be canceled particularly when the sponsor feels that its questions have been adequately answered by the FDA in writing.

84. On November 22, 2017, Meier-Davis provided the FDA's Comments to Jacobson-Kram. After reviewing the FDA's Comments, Jacobson-Kram did not indicate that he thought an RTF was a probability. Rather, he felt there was a "likely" chance that the FDA would accept Celgene's nonclinical carcinogenicity studies.

85. On the same day, Meier-Davis provided Wood with the FDA's Comments. Wood responded that Celgene should not offer to conduct additional nonclinical studies. Meier-Davis forwarded Wood's response to Martin and noted that the "FDA did not have the full package for review at the time of briefing book" because Celgene's NDA would contain additional nonclinical data concerning the Metabolite from certain "bridging studies." As Dr. McGuinn explains, the bridging studies were short-term supplemental studies, in which Celgene administered Ozanimod directly to animals, which provided Celgene with additional Metabolite exposure data.

86. On November 22, 2017, Tran sent Palmisano the FDA Comments and stated, "[i]n short, the FDA requested the full CSR (instead of the proposed abbreviated CSR) for the study RPC01-1001... we are confident we can provide the full CSR at the NDA submission. With that,

we will be able to complete the Clin Pharm package for the NDA filing." Palmisano responded that this was "great news" and that the FDA's Comments were otherwise not concerning.

87. On November 22, 2017, Lamb sent the FDA's Comments to Gondi Kumar ("Kumar"), Celgene's Corporate Vice President for Nonclinical Development and the internal subject matter expert for nonclinical development. Lamb asked Kumar whether the Metabolite was qualified across all studies, which Kumar confirmed. Kumar noted that the FDA had previously approved Celgene's designs for its nonclinical carcinogenicity studies, including the doses administered in such studies. At no point did the FDA rescind such approval.

88. Following receipt of the FDA's Comments, Lamb put together a risk assessment "tracker," which was a typical assessment done in the normal course of preparing any NDA. The tracker identified certain potential RTF issues and noted how Celgene planned to mitigate those issues in the NDA.

89. Lamb sent a copy of the tracker to Houn. Houn did not know how Celgene addressed the FDA's Comments in the NDA nor did she know what information Celgene ultimately included in the NDA submission.

90. On or around November 30, 2017, Martin presented about the FDA's Comments to the IIEC, which included Curran. At the meeting, Martin presented a slide deck, which noted that "[t]he FDA feedback received was generally in line with the team's expectations" and "the NDA remains on target and will be submitted on time, by the end of the year." The slide deck included Celgene's plan for the NDA following the FDA's Comments. One of the slides presented stated that Celgene would "submit [the] full CSR (including the bioanalytical data and validation reports) for the study RPC01-1001 and all relevant clinical PK and PD studies and population PK and ER analyses the time of the NDA submission." As to nonclinical data for the Metabolite, a slide

presented stated that "exposure levels will be final, not estimated, and will be included as part of the [NDA] submission." This slide noted that the Metabolite was "adequately assessed in general and reproductive toxicity studies" and Celgene had "supportive data" as to the adequate assessment of its carcinogenicity studies. The presentation also noted that, according to "feedback from ex-FDA reviewers," additional carcinogenicity studies should not be necessary. As to LTS data, the slide deck noted, that "Celgene will... [p]rovide data on the short-term stability of [the Metabolite] in human plasma at the time of the NDA submission, followed by long-term stability data in the future." Martin sent the slide deck from his IIEC presentation to S. Smith.

91. On December 12, 2017, Brett Skolnick, Celgene's Executive Director of Clinical Development, sent Katz the FDA Comments and stated "[b]ased on the FDA response we opted to not meet [face-to-face] since we felt that the vast majority of our issues were addressed in their response. However, we would welcome your review and comments to ensure we didn't miss any nuance that might require attention."

92. On December 13, 2017, Lamb sent draft FDA guidance titled "Refuse to File: NDA and BLA Submissions to CDER" to Backstrom and Curran and informed them that the draft guidance did not change the current assessment for the Ozanimod NDA.

93. On December 14, 2017, Celgene received Katz's feedback on the FDA's Comments. Katz did not raise concerns that there would be a risk of an RTF if Celgene proceeded with submitting the NDA. Indeed, he relayed that the FDA's use of "matter of review" in the FDA's Comments meant that Celgene would not receive an RTF, although the data would be relevant to approvability.

15. Celgene's CMO and its Internal Regulatory Experts, Among Others, Agree the NDA is Ready to Submit to FDA

94. Martin's job "was to make sure that the team was working on the submission and was able to get the best product out and then for Celgene to decide whether this product met all the necessary requirements for us to file." His responsibilities did not include approving the NDA for submission.

95. S. Smith "had the NDA reviewed by [Backstrom] and [then Backstrom] made a recommendation to Mark Alles and [S. Smith] that the NDA was ready to go and green-lighted it."

96. Part of Backstrom's "responsibilities included looking at the [Ozanimod NDA] and making a decision that it was ready to submit … to the FDA." Backstrom consulted Celgene's subject matter experts, Palmisano and Kumar, following their review of the NDA. Palmisano informed Backstrom that she "assess[ed] the [NDA] as having minimal risk of RTF on the basis of the metabolite." Kumar informed Backstrom that with respect to qualification of the Metabolite, "we are well covered." According to Backstrom, "[t]he general opinion was there was sufficient information to guide FDA at the time that this submission went in. [] Clinical pharmacology technical experts looked at this, thought that we had enough in there to guide FDA toward an approval and toward product labeling [-] that's why it went in [to FDA]."

97. On December 20, 2017, Backstrom emailed Alles and S. Smith, copying Martin, Curran, and others, stating, "the ozanimod team has been working heroically to bring the submission in this year taking into consideration the FDA feedback from the November meeting indicating the need for the final CSR from the PK RC01-1001 study. The PK CSR has been finalized and is now with Regulatory Operations for publishing. I just completed a call with [Martin], [Lamb] and [Curran] (after consulting with Maria Palmisano earlier today) and am [in]

agreement with the assessment that once publishing has been completed the submission is ready to go."

98. Curran responded to Backstrom's email congratulating the team and stated that she was looking forward to the launch of Ozanimod. Curran "had confidence in the expertise that [Celgene] had internally" and she understood that the "external experts" had "agreed with [Celgene's] strategy."

16. Celgene Submits the Ozanimod NDA to the FDA

99. On December 22, 2017, following the internal review of the NDA at Celgene and the determination that it was ready, Celgene submitted the Ozanimod NDA to the FDA.

100. In its NDA submission, Celgene included a full CSR for RPC01-1001. Indeed, as Dr. Sherry explains, all the CSRs submitted as part of Celgene's clinical pharmacology package were "full" CSRs, which included bioanalytical and validation reports.

101. In its NDA submission, Celgene included evidence of stability for the Metabolite for RPC01-1001, which was a Phase I study.

102. In its NDA submission, Celgene included final, not estimated, exposure levels to the Metabolite for the entire dose range tested. Celgene also provided data from its nonclinical bridging studies. As Dr. McGuinn explains, the data from the bridging studies demonstrated adequate exposure to the Metabolite. Moreover, Celgene's data in its NDA demonstrated that it was not possible to achieve higher exposures to the Metabolite because the required dose to do so would kill the animals in the studies.

17. The January and February 2018 Statements

103. At the time that Celgene issued the January and February 2018 statements stating that the NDA had been submitted, Curran and S. Smith understood that the NDA had addressed

the FDA's Comments and that Celgene's external experts, internal subject matter experts, and CMO, among others, agreed that the NDA had been ready to submit to the FDA.

104. Following these statements, analysts recognized that there was still inherent uncertainty as to the regulatory outcome of the Ozanimod NDA. For example, on January 25, 2018, a SunTrust Robinson Humphrey report noted that Ozanimod "could face clinical and regulatory setbacks." On February 15, 2018 an Oppenheimer report identified a potential "downside scenario" wherein Ozanimod could "fail[] to gain FDA approval."

18. Celgene Receives an RTF from the FDA

105. Days before the RTF issued, a draft press release that Curran sponsored was sent to S. Smith and Backstrom in which Celgene planned to announce the FDA's filing of the NDA.

106. The clinical pharmacology component of the RTF provided that the LTS of the Metabolite "has not yet been established. Retained plasma samples were used to quantify [the Metabolite] in studies RPC01-201 (Part A and B), RPC01-301, RPC01-1904, RPC01-1906 and RPC01-1001" and "samples were analyzed outside of the long-term stability window (136 days)" for the Metabolite.

107. Because Celgene included full CSRs for all studies, the FDA did not cite a lack of CSRs as a reason for the RTF. Indeed, the RTF makes no mention of CSRs.

108. The nonclinical component provided that Celgene "will need to demonstrate that RP112273 has been assessed in a standard battery of nonclinical studies. To bridge to the existing nonclinical data, you would need to demonstrate adequate plasma RP112273 exposures in males and females, using the same dosing regimens used in the pivotal studies, in all species tested."

109. Nowhere in the RTF did the FDA indicate that Celgene failed to include final (as opposed to estimated) exposure data for the Metabolite, much less identify that as a reason for the RTF. The RTF also did not mention Total Agonist data or identify it as a reason for the RTF.

110. At Celgene, the RTF was a shocking result. Saillot testified that "none of us were expecting... an RTF, and that was a shock to everybody." According to Backstrom, no one "thought there would be an RTF on the basis of [the NDA]." Lamb was "shocked" because Celgene "had provided a complete NDA that would allow for an FDA extensive review." Curran was "shocked" as was S. Smith "given the internal/external advice that [Celgene] had received relative to the filing."

111. When Lesko "learned of the RTF … [he] was surprised" because "the clin pharm workup of this drug was very good."

112. On March 9, 2018, Celgene requested a meeting with the FDA, which the FDA granted and scheduled for April 3, 2018.

113. In connection with the April 3 meeting, the FDA would not identify an exposure multiple that the agency considered "adequate," which is consistent with the ICH Q&A not mandating that a certain exposure multiple be achieved. The FDA also said that it was appropriate for Celgene to rely on the highest dose tested to calculate exposure multiples. Moreover, the FDA informed Celgene that exposure multiples are not reviewed in isolation but rather in the context of the "totality of the nonclinical and clinical data" and that sponsors should not "conduct unnecessary animal studies."

114. On April 25, 2018, Celgene disclosed the Metabolite during a presentation at the American Academy of Neurology Annual Meeting. After this information was disclosed, Celgene's stock did not drop.

19. Morgan Stanley Inaccurately Predicts a One to Three Year Delay for Celgene to Refile Its Ozanimod NDA Based on Celgene Re-Doing Certain Nonclinical Studies

115. On April 26, 2018, Jefferies issued an analyst report entitled, "New Ozanimod RTF Questions Will Continue to Linger.… We'll Find Out More May 4." The Jefferies report discussed

preclinical toxicology studies that could take up to two years and discussed why these additional studies could be necessary. Specifically, the Jefferies report stated, "Bears will say: insufficient tox[icology] coverage for this metabolite which is the actual active moiety, FDA guidance suggests needs 1-2 years more preclinical studies, brings high uncertainty even if NDA filing - whether Ozanimod would actually get approved and/or now has hair on it.... The question for investors is whether CELG has sufficient information at this point or at least soon and can re-file this year (positive for stock), or whether they need to run longer term 1-2 year tox[icology] and carcinogenicity studies that mean a re-filing could be pushed out 1-2 years (negative for stock...-5-10%)."

116. After this information was disclosed, Celgene's stock price did not decline.

117. The April 29, 2018 Morgan Stanley report stated that its analysis of prior published data from Ozanimod's nonclinical studies suggested that the Metabolite "concentrations in prior pre-clinical work [are] unlikely to approximate human clinical doses" and therefore that it "believe[d] it is increasingly likely mgt. will need to complete new preclinical work on [the Metabolite] setting up a 1 to 3 year delay." The one to three year delay was predicted because "mgt. will likely need to rerun preclinical toxicology which could take 6 months (rats) to 2 years (another carcinogenicity study)," and Morgan Stanley contemplated a scenario under which "mgt. must redo all animal work."

118. On May 2, 2018, Morgan Stanley corrected its April 29, 2018 report and revised and shortened its predicted delay to "1-1.5yrs" after consulting with two "experts."

20. Celgene Resubmits the Ozanimod NDA Without Providing Evidence of LTS for the Metabolite for Every Phase III Study Sample or Re-Doing Its Nonclinical Pivotal Studies, and the FDA Approves the NDA

119. In connection with the rNDA, Celgene did not provide evidence of LTS for the Metabolite for every sample in the Phase III studies. Rather, the FDA accepted 17 months of LTS data.

120. Contrary to the predictions in the April 29, 2018 Morgan Stanley analyst report, Celgene did not have to rerun any pivotal toxicology studies in rats or otherwise, nor conduct another carcinogenicity study.

121. Indeed, in its rNDA, Celgene continued to rely on the same pivotal toxicology studies that Celgene submitted with the original NDA to demonstrate that the Metabolite had been adequately assessed.

122. In connection with its review of the rNDA, although the FDA noted that exposure to the Metabolite was "lower" in certain studies, the FDA nonetheless concluded that the "safety profile is acceptable in light of the serious nature of the disease being treated." The FDA recognized that it was not possible for Celgene to obtain higher exposure to the Metabolite based on short duration bridging studies, some of which had been included in the original NDA submission. As Dr. McGuinn explains, given the extensive data Celgene provided in the original NDA, the FDA could have allowed Celgene to conduct any further bridging studies concurrent with the agency's review of the original NDA submission, with the stipulation that Celgene submit the reports for these studies before the FDA finished its review of the NDA.

123. In connection with its review of the rNDA, the FDA initially contemplated approving the rNDA with a post-marketing requirement concerning a different metabolite, CC1084037, since Celgene lacked "sufficient exposure" to it in one of its studies. Although the FDA ultimately determined that this post-marketing commitment was unnecessary, Dr. McGuinn

explains that the FDA could have reached a similar decision with regarding to the nonclinical package in the original NDA submission.

124. On March 25, 2020, the FDA approved Ozanimod for the treatment of adults with relapsing forms of MS. Ozanimod is now on the market as Zeposia.

125. The Zeposia label warned that based on the results from nonclinical animal studies, the drug may cause fetal harm, which is consistent with Celgene not needing additional exposure to the Metabolite in Celgene's rabbit embryo-fetal development study because the study had demonstrated that Ozanimod was an embryo-fetal toxin. The label also warned that the drug caused an increase in cancer in mice, which is consistent with Celgene not needing additional exposure to the Metabolite in Celgene's 6-month mouse study because the carcinogenic potential of the drug had been adequately characterized.

126. The FDA also addressed certain deficiencies in the development program for ozanimod in labeling. For example, the label warned that the use of Zeposia in patients with hepatic impairment is "not recommended" because the effect on the pharmacokinetics of the Metabolite is unknown. As Dr. Sherry explains, the FDA could have applied this same labeling approach to address the characterization of the Metabolite in the original NDA submission.

21. No Defendant Was Motivated to Commit Securities Fraud

127. Celgene leadership was not motivated to submit the NDA because of potential bonuses. Celgene executives were not automatically entitled to a bonus simply because the Ozanimod NDA was filed in 2017. Bonuses required the achievement of several milestones and neither the completion of (or failure to complete) any single milestone guaranteed a particular bonus amount. As Martin explained, he, and the other executives, could have achieved 100% of the bonus without submitting the NDA.

128. Moreover, Celgene was not motivated to file a deficient NDA to replace revenue or ensure financial success. A rejected NDA means Celgene cannot sell the product and it cannot then generate any revenue from the new product candidate, replacement or otherwise. Nor can a product that is not approved and not on the market fend off competition from other entrants to that market.

C. Defendants intend to prove the following contested facts with regard to damages. (This statement must include the factual basis for each defense against plaintiff's claims for damages).

1. Plaintiff Cannot Prove Damages with Respect to Otezla

1. Plaintiff's expert, Dr. David Tabak, has failed to reliably measure inflation (if any) or establish loss causation with respect to Otezla. Dr. Tabak's analysis with respect to Otezla is flawed and overstates inflation (if any) for several reasons.

2. First, Dr. Tabak's attempt to apportion the October 26, 2017 price decline to the "news regarding Otezla" is flawed and unsupported. Dr. Tabak's analysis implicitly assumes that a dollar of Celgene's 2021 revenue from any product or division would contribute equally to Celgene's value; however, he has provided no basis for this assumption. Additionally, Dr. Tabak's calculation of the $13.61 per share inflation related to Otezla is flawed because in his calculations, Dr. Tabak omits 2021 revenue projections for Otezla issued by one of the analysts, SunTrust Robinson Humphreys.

3. Second, in analyzing the price decline on October 26, 2017, Dr. Tabak fails to take into account the impact of confounding information related to revised expectations for 2020 Otezla revenue which is not at issue in this case. Accordingly, revisions to 2020 revenue guidance for the I&I division, which included Otezla, disclosed in the earnings press release dated October 26, 2017, would constitute confounding information. However, Dr. Tabak has provided no analysis to separate the price decline, if any, on October 26, 2017 that is attributable to revisions in the 2017

revenue guidance for Otezla from the price decline on October 26, 2017 that is attributable to revised expectations for the 2020 revenue for Otezla. Indeed, Dr. Tabak ignores that only a small portion of the price decline, if any, on October 26, 2017 could be attributable to the updates to 2017 revenue guidance for Otezla. Accordingly, his estimate of $13.61 per share overstates the inflation, if any, related to Otezla in Celgene's stock price.

4. Third, Dr. Tabak ignores that the price decline on October 26, 2017 would reflect, at least in part, the materialization of a known risk that the 2017 revenue guidance for Otezla would not be met or would be revised. The risk that the 2017 revenue guidance for Otezla would not be met was known to the market prior to the October Disclosure. Thus, even if one were to assume that the entire $13.61 of the price decline on October 26, 2017 is attributable to "news regarding Otezla," at least part of that $13.61 price decline reflects the materialization of a known risk that the 2017 revenue guidance for Otezla would not be met. Accordingly, Dr. Tabak's estimate of $13.61 per share overstates the inflation, if any, related to Otezla in Celgene's stock price.

5. Fourth, Dr. Tabak fails to appropriately account for changes in inflation (to the extent there is any) related to Otezla, during the Class Period. He claims to account for changes in inflation related to Otezla over the Class Period using his "scaling" analysis. However, he ignores that Celgene's internal forecast for 2017 Otezla sales (through October 3, 2017) that he relies upon for his analysis was consistent with the 2017 revenue guidance for Otezla that Celgene had communicated to the market prior to the October Disclosure. Moreover, the scaling analysis he relies on is based on the unsupported assumption that future sales can be predicted based solely on prior period sales.

6. Fifth, Dr. Tabak ignores that the October Disclosure regarding the revision of 2017 revenue guidance for Otezla, was made against the backdrop of the setback regarding another of

Celgene's drugs, GED-0301. This resulted in increased scrutiny on the Company. Thus, he fails to take into account that the price reaction to the October Disclosure may have been different from the price reaction to the same disclosure made earlier in the Class Period.

7. Dr. Tabak has also failed to account for the mismatch between the alleged corrective information disclosed in the October Disclosure and Curran's July Statement. Given this mismatch, Dr. Tabak has failed to reliably establish loss causation with respect to the July Statement.

2. Plaintiff Cannot Prove Damages with Respect to Ozanimod

8. As an initial matter, Plaintiff did not purchase any shares of Celgene following any of the challenged Ozanimod statements. For that reason, Plaintiff will be unable to prove damages with respect to Ozanimod (and otherwise lacks standing to pursue its Ozanimod claims).

9. Additionally, similar to Otezla, Dr. Tabak has failed to reliably measure inflation (if any) or establish loss causation with respect to Ozanimod. Dr. Tabak's analysis with respect to Ozanimod is flawed and overstates inflation (if any) for several reasons.

10. First, Dr. Tabak fails to consider that Celgene had not yet identified the Metabolite at the start of the Class Period nor that, even with the presence of the Metabolite, an RTF was not an inevitable outcome. Thus, Dr. Tabak has not taken into account the disconnect between the alleged misrepresentation (failure to disclose the existence of the Metabolite and "meaningful information as to the Metabolite vis-à-vis the NDA") and the alleged corrective disclosure on February 27, 2018 (receipt of the RTF). Accordingly, Dr. Tabak has failed to reliably establish loss causation with respect to the alleged corrective disclosure on February 27, 2018.

11. Second, Dr. Tabak has not established that the price decline on February 28, 2018 can be attributed to the correction of alleged misrepresentations regarding Ozanimod rather than the materialization of a known risk that delays or rejections could occur during the regulatory

approval process for Ozanimod. Celgene disclosed risk factors regarding the regulatory approval for products in the development stage prior to the alleged corrective disclosure on February 27, 2018. For example, in its Q1 2017 10-Q, issued on the first day of the Class Period, Celgene discussed risks related to "[d]elays or rejections [that] may be encountered during any stage of the regulatory process if the clinical or other data fails to demonstrate compliance with a regulatory agency's requirements for safety, efficacy and quality." Moreover, before the RTF was issued, analysts were aware that Ozanimod's success was not guaranteed. For example, after commenting on Ozanimod's positive Phase III MS data, Cantor Fitzgerald nevertheless noted significant uncertainty regarding Ozanimod's FDA approval process:

> [O]zanimod's cardiac profile looked compelling, possibly positioning the drug for a cleaner label versus Gilenya. However, given that this is an unknown until the FDA signs off, we think it will be difficult for investors to assume such an outcome amid the backdrop of the newly released lower long-term guidance.

Similarly, RBC highlighted the potential failure of Ozanimod as one of several "[k]ey risks" and a factor in their "[d]ownside scenario." Credit Suisse noted the removal of Ozanimod from the pipeline as an assumption in their "grey sky scenario." And in multiple reports, Zacks noted that:

> ... clinical development involves a high degree of risk. Gaining approval for pipeline candidates has become more difficult amid the tough regulatory environment.

12. Third, Dr. Tabak's estimate of inflation (if any) that dissipated from Celgene's stock price on February 28, 2018 is flawed because he ignores that the price reaction following the alleged corrective disclosure on February 27, 2018 could have reflected other broader concerns about the company, including a series of recent, unexpected setbacks: a) the failure of one of Celgene's pipeline drugs announced on October 19, 2017; b) the 2020 revenue guidance reduction announced on October 26, 2017, and c) the delayed timeline for Ozanimod in ulcerative colitis announced on October 26, 2017. Indeed, analysts noted that the repeated setbacks, in conjunction

with the RTF news, had led to additional concerns about Celgene, including management credibility and management execution.

13. Dr. Tabak fails to establish that the information in the alleged "but-for" disclosure was not already known to the market and fails to identify the information that Defendants allegedly could and should have disclosed instead of the alleged misrepresentations. Dr. Tabak cannot show that the Morgan Stanley report provided information not already known to the market, in light of the April 26, 2018 Jefferies report which discussed the same type of study and of the same duration contemplated by Morgan Stanley in the April 29, 2018 report. Moreover, to the extent that Celgene *did not need* to run either of the preclinical toxicology studies noted by Morgan Stanley, Dr. Tabak has failed to take into account that Celgene could not have disclosed the *need* to run those studies.

VI. PLAINTIFF'S WITNESSES (Aside from those called for impeachment purposes, only those witnesses whose names and addresses are listed below will be permitted to testify at trial).[3]

A. On liability, plaintiff intends to call the following witnesses who will testify in accordance with the following summaries:

1. Witness: **Betty Jean Swartz**

Address: 2021 Sweetgum Lane, Collegeville, Pennsylvania 19426

Live/By Videotaped Deposition[4]: Live

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[3] The parties continue to meet and confer regarding trial witnesses and evidentiary issues and retain the right to identify record custodians as trial witnesses and/or to submit evidentiary certifications if necessary due to unresolved evidentiary objections.

[4] The designation of "Live" or "By Videotaped Deposition" is based on Plaintiff's current understanding as to whether a particular witness is within the subpoena power of the Court or is otherwise available for trial, or whether the witness's deposition may be otherwise introduced pursuant to Rule 32.

Summary of Testimony:[5] During the Class Period, Ms. Swartz served as Celgene's Vice President of Market Access and will describe Celgene's market access strategy for Otezla through its entry into managed care contracts, including the known challenges and costs associated with those contracts and with growing Otezla's market share and net sales. Ms. Swartz will also testify that Terrie Curran and other senior Celgene executives were warned directly, on multiple occasions, of the risk that Celgene would not meet its 2017 Otezla forecast. Ms. Swartz will also testify about Otezla's performance in the first half of 2017.

2. Witness: **Chris Stomberg**

Address: C/O Bernstein Litowitz Berger & Grossmann LLP

Live/By Videotaped Deposition: Live

Summary of Testimony: Dr. Stomberg is an expert witness who will describe industry norms regarding pharmaceutical forecasting practices, review and opine upon Celgene's forecasting practices in connection with setting Otezla's 2017 budget, and review and opine upon Otezla's 2017 performance in relation to market performance metrics relied upon by Celgene and other industry participants. Dr. Stomberg will also testify on points related to the foregoing topics and/or in response to testimony from Defendants' expert witnesses, as necessary.

3. Witness: **David Kao**

Address: 4900 Bridle Ridge Court, San Diego, California 92130

Live/By Videotaped Deposition: Deposition

Summary of Testimony: During the Class Period, Mr. Kao was the Executive Director of Regulatory Affairs at Receptos. Under Fed. R. Civ. P. 32(a)(4), Plaintiff expects to

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[5] The summaries included herein are intended to be a brief, high-level summary of the topics and issues that Plaintiff anticipates each witnesses' testimony will address. Plaintiff reserves the right to elicit testimony about any other issues in accordance with the Federal Rules of Evidence.

present excerpts from Mr. Kao's deposition concerning his review of regulatory precedent related to the non-clinical portion of the Ozanimod NDA, the status of the Ozanimod NDA submission, communications from Celgene's external consultants regarding the testing and data for the Ozanimod NDA, and the financial incentives for Celgene personnel related to the submission of the Ozanimod NDA.

4. Witness: **David Wilson**

Address: 12726 Triumph Drive, Poway, California 92064

Live/By Videotaped Deposition: Deposition

Summary of Testimony: During the Class Period, Mr. Wilson was a clinical bioanalytical lead at Receptos. Under Fed. R. Civ. P. 32(a)(4), Plaintiff expects to present excerpts from Mr. Wilson's deposition concerning Celgene's discovery of 273 and the implications of that discovery, Celgene's clinical pharmacology testing and studies for Ozanimod, including 273 LTS testing, and the clinical pharmacology portion of the Ozanimod NDA.

5. Witness: **David Tabak**

Address: C/O Kessler Topaz Meltzer & Check LLP

Live/By Videotaped Deposition: Live

Summary of Testimony: Dr. Tabak is an expert witness who will serve as Plaintiff's expert on loss causation and damages and will provide testimony that each of the alleged corrective disclosures resulted in losses to investors; describe a method for estimating investors' per-share losses and recoverable per-share damages; opine as to a reasonable estimate of investors' per-share losses and recoverable per-share damages; and provide additional testimony relevant to materiality and reliance.

6. Witness: **Document Reader**

Address: C/O Kessler Topaz Meltzer & Check LLP

Live/By Videotaped Deposition: Live

Summary of Testimony: Employee or agent of Plaintiff's counsel may read documents into the record that are otherwise admissible.

7. Witness: **Douglas Bressette**

Address: Annandale, New Jersey

Live/By Videotaped Deposition: Live

Summary of Testimony: During the Class Period, Mr. Bressette served as a Senior Director of Global Business Planning and Analysis for Celgene's I&I Franchise and will testify generally about Otezla's budget and forecasting process and its performance in the first half of 2017. Mr. Bressette will also testify about contemporaneous documents and his communications with Terrie Curran and other Celgene executives regarding Otezla's market share, inventory, run rate, and other performance metrics.

8. Witness: **Florence Houn**

Address: 10001 Ormond Road, Potomac, Maryland 20854

Live/By Videotaped Deposition: Deposition

Summary of Testimony: During the Class Period, Dr. Houn was Vice President of Global Regulatory Science at Celgene. Under Fed. R. Civ. P. 32(a)(4), Plaintiff expects to present excerpts from Dr. Houn's deposition concerning the status of the Ozanimod NDA and Celgene's communications with the FDA regarding the Ozanimod NDA.

9. Witness: **Frederick Guengerich**

Address: C/O Kessler Topaz Meltzer & Check LLP

Live/By Videotaped Deposition: Live

Summary of Testimony: Dr. Guengerich is an expert witness who is expected to testify concerning: (1) drug metabolism, including the metabolism of Ozanimod; (2) the identification, characterization, and safety testing of drug metabolites, including 273; (3) toxicology principles and animal toxicology studies; (4) drug exposure and exposure multiples; (5) LTS testing; (6) FDA and ICH Guidance regarding metabolites and LTS testing; and (7) Celgene's compliance with FDA Guidance and industry standards, customs, and practices concerning non-clinical toxicology and LTS testing. Dr. Guengerich will also testify on points related to the foregoing topics and/or in response to testimony from Defendants' expert witnesses, as necessary.

10. Witness: **Gerlee Thomas**

Address: 6974 Shoreline Drive, Carlsbad, California 92011

Live/By Videotaped Deposition: Deposition

Summary of Testimony: During the Class Period, Ms. Thomas was Director of Regulatory Affairs at Celgene. Under Fed. R. Civ. P. 32(a)(4), Plaintiff expects to present excerpts from Ms. Thomas' deposition concerning the financial incentives for Celgene personnel related to the submission of the Ozanimod NDA.

11. Witness: **Hunter Smith**

Address: 17 Myanos Road, New Canaan, Connecticut 06840

Live/By Videotaped Deposition: Deposition

Summary of Testimony: During the Class Period, Mr. Smith served as the Vice President of Finance for Celgene's I&I Franchise. Under Fed. R. Civ. P. 32(a)(4), Plaintiff expects to present excerpts from Mr. Smith's deposition concerning Celgene's process in creating the 2017

Otezla Budget, the metrics relevant to assessing budget and forecast performance, and specific documents and communications with Terrie Curran and other Celgene executives regarding Otezla's performance in the first half of 2017.

12. Witness: **James Kilgallon**

Address: 6 Evans Lane, Bridgewater, New Jersey 08807

Live/By Videotaped Deposition: Live

Summary of Testimony: During the Class Period, Mr. Kilgallon served as Celgene's Executive Director of Pricing and Contracting and will testify about Celgene's market access strategy for Otezla through its entry into managed care contracts, including the known challenges and costs associated with those contracts and with growing Otezla's market share and net sales. Mr. Kilgallon will also testify that Terrie Curran and other senior Celgene executives were warned of the risk that Celgene would not meet its 2017 Otezla forecast. Mr. Kilgallon will also testify about Otezla's performance in the first half of 2017.

13. Witness: **James MacDonald**

Address: 7 Deer Hill Road, Chester, New Jersey 07930

Live/By Videotaped Deposition: Live

Summary of Testimony: Dr. MacDonald is a founding partner at Synergy Partners R&D Solutions. Plaintiff expects that Dr. MacDonald will testify concerning the non-clinical section of Celgene's Ozanimod NDA, including the toxicology testing and studies and exposure multiples for 273, Celgene's communications with the FDA regarding the Ozanimod NDA, and his communications with Celgene regarding these subjects.

14. Witness: **Jean-Louis Saillot**

Address: 450 Santa Dominga, Solana Beach, California 92075

Live/By Videotaped Deposition: Deposition

Summary of Testimony: During the Class Period, Dr. Saillot was Celgene's Vice President of Project Leadership, Regulatory Affairs, and Clinical Pharmacology at Receptos. Under Fed. R. Civ. P. 32(a)(4), Plaintiff expects to present excerpts from Dr. Saillot's deposition concerning Celgene's discovery of 273 and the implications of that discovery; Celgene's clinical pharmacology and non-clinical testing and studies for Ozanimod; the clinical pharmacology and non-clinical portions of the Ozanimod NDA; Celgene's communications with the FDA regarding the Ozanimod NDA; and Celgene's communications with its external consultants regarding the testing and data for the Ozanimod NDA.

15. Witness: **Jonathan Tran**

Address: 1752 West Lewis Street, San Diego, California 92103

Live/By Videotaped Deposition: Deposition

Summary of Testimony: During the Class Period, Mr. Tran was the Executive Director of Clinical Pharmacology at Receptos. Under Fed. R. Civ. P. 32(a)(4), Plaintiff expects to present excerpts from Mr. Tran's deposition concerning Celgene's discovery of 273 and the implications of that discovery; Celgene's clinical pharmacology testing and studies for Ozanimod, including LTS testing; the clinical pharmacology portion of the Ozanimod NDA; and Celgene's communications with the FDA regarding the Ozanimod NDA.

16. Witness: **Matthew Lamb**

Address: 42 Kings Highway, Long Valley, New Jersey 07853

Live/By Videotaped Deposition: Live

Summary of Testimony: During the Class Period, Mr. Lamb was Celgene's Vice President and Global Head of Regulatory Affairs in I&I. Plaintiff expects that Mr. Lamb will

testify concerning the relationship between Celgene and Receptos; Celgene's discovery of 273 and the implications of that discovery; Celgene's clinical pharmacology and non-clinical testing and studies for Ozanimod; the clinical pharmacology and non-clinical portions of the Ozanimod NDA; Celgene's communications with the FDA regarding the Ozanimod NDA; Celgene's potential use of a priority review voucher for Ozanimod; and Celgene's communications with its external consultants regarding the testing and data for the Ozanimod NDA.

17. Witness: **Nicholas Fleischer**

Address: C/O Kessler Topaz Meltzer & Check LLP

Live/By Videotaped Deposition: Live

Summary of Testimony: Dr. Fleischer is an expert witness who is expected to testify concerning: (1) FDA guidance and FDA and industry customs and practices regarding the submission, review, and approval/rejection of NDAs submitted to the FDA, including guidance and industry customs and practices regarding LTS testing and data; (2) Celgene's compliance with FDA guidance and industry customs and practices, including FDA guidance and industry customs regarding the submission of complete LTS data, and the FDA's correspondence regarding the submission of LTS data; (3) the risk of a refusal to file resulting from incomplete clinical pharmacology data, including LTS. Dr. Fleischer will also testify on points related to the foregoing topics and/or in response to testimony from Defendants' expert witnesses, as necessary.

18. Witness: **Philippe Martin**

Address: 5628 Waverly Ave., San Diego, California 92037

Live/By Videotaped Deposition: Live

Summary of Testimony: During the Class Period, Defendant Martin was Celgene's Corporate Vice President and the Managing Director of Celgene-Receptos in San Diego. Plaintiff

expects that Martin will testify concerning his statements during Celgene's panel at ECTRIMS on October 28, 2017; the relationship between Celgene and Receptos; Celgene's discovery of 273 and the implications of that discovery; Celgene's clinical pharmacology and non-clinical testing and studies for Ozanimod; the clinical pharmacology and non-clinical portions of the Ozanimod NDA; Celgene's communications with its external consultants regarding the testing and data for the Ozanimod NDA; and Celgene's communications with the FDA regarding the Ozanimod NDA.

19. Witness: **Robert Tessarolo**

Address: 562 Hidden Trail, Oakville, Ontario, Canada L6M 0N3

Live/By Videotaped Deposition: Deposition

Summary of Testimony: Mr. Tessarolo served as General Manager of Celgene's I&I Franchise. Under Fed. R. Civ. P. 32(a)(4), Plaintiff expects to present excerpts from Mr. Tessarolo's deposition concerning the financial impact of the end of patent protection for Revlimid and Otezla performance trends shared with Terrie Curran in 2016.

20. Witness: **Scott Smith**

Address: 18501 Collins Ave., Sunny Isles, Florida 33160

Live/By Videotaped Deposition: Deposition

Summary of Testimony: Scott Smith was the President of Celgene I&I and the Chairman of the IIEC from 2010 until April 2017, at which point Smith became President and COO of Celgene through the end of the Class Period. Under Fed. R. Civ. P. 32(a)(3) or (a)(4) Plaintiff expects to present excerpts from Mr. Smith's deposition concerning Celgene's quarterly disclosure process related to Celgene's public statements during the Class Period; Celgene's management incentive plan; Celgene's internal forecasts, budgets, and public guidance for Otezla; Celgene's discovery of 273 and the implications of that discovery; Celgene's communications with

the FDA regarding the Ozanimod NDA; Celgene's potential use of a priority review voucher for Ozanimod; Celgene's receipt of an RTF letter from the FDA for the Ozanimod NDA; and Smith's agreements with Celgene in connection with his departure from the Company.

21. Witness: **Simon Helfgott**

Address: C/O Kessler Topaz Meltzer & Check LLP

Live/By Videotaped Deposition: Live

Summary of Testimony: Dr. Helfgott is an expert witness who will testify concerning the available treatments for psoriasis and psoriatic arthritis during the Class Period; Otezla's low efficacy, poor tolerability, and high discontinuation rate compared to other available treatments during the Class Period; Otezla's inferiority as a systemic treatment for psoriasis and psoriatic arthritis given its efficacy, tolerability, side effects, and costs relative to other available treatments during the Class Period; and describe the factors that physicians may consider when selecting a systemic treatment for a patient with psoriasis or psoriatic arthritis. Dr. Helfgott will also testify on points related to the foregoing topics and/or in response to testimony from Defendants' expert witnesses, as necessary.

22. Witness: **Steven Rosen**

Address: 6 Winding Brook Way, Titusville, New Jersey 08560

Live/By Videotaped Deposition: Live

Summary of Testimony: During the Class Period, Mr. Rosen served as Celgene's Executive Director of Corporate Financial Planning and Analysis and will testify about Celgene's process of setting the Otezla budget and forecasts; the relationship between the budget and performance expectations; Celgene's Corporate Finance Group's process for tracking sales trends; Otezla's sales trends and performance in the first and second quarters of 2017; his communications

with Celgene executives about drivers of Otezla's performance; and the market's reaction to Celgene's lowering Otezla's guidance on October 26, 2017.

23. Witness: **Susan Meier-Davis**

Address: 13552 Del Poniente Rd., Poway, California 92064

Live/By Videotaped Deposition: Deposition

Summary of Testimony: During the Class Period, Dr. Meier-Davis was a Senior Director in Pre-Clinical Sciences at Receptos. Under Fed. R. Civ. P. 32(a)(4), Plaintiff expects to present excerpts from Dr. Meier-Davis' deposition concerning Celgene's discovery of 273 and the implications of that discovery; Celgene's non-clinical testing and studies for Ozanimod; the non-clinical portions of the Ozanimod NDA, including the toxicology testing and studies and exposure multiples for 273; Celgene's communications with the FDA regarding the Ozanimod NDA; and Celgene's communications with its external consultants regarding the testing and data for the Ozanimod NDA.

24. Witness: **Terrie Curran**

Address: C/O Jones Day

Live/By Videotaped Deposition: Deposition

Summary of Testimony: Plaintiff expects to present deposition testimony pursuant to Fed. R. Civ. P. 32(a)(3) from Defendant Terrie Curran, former Head of Worldwide Markets for Celgene's I&I franchise from March 2016 through April 1, 2017, and President of I&I and the Chairwoman of the IIEC from April 1, 2017 through the end of the Class Period. The deposition excerpts include testimony about the preparation of Celgene's 2017 Otezla budget, Otezla's performance from the second half of 2016 through the second quarter of 2017, Curran's knowledge of specific Otezla performance metrics (including market share, market growth, inventory, net

sales, new patient growth, managed care contracts), and Curran's public statements regarding Otezla. Ms. Curran's deposition testimony also addresses Celgene's discovery of 273 and the implications of that discovery; Celgene's communications with the FDA regarding the Ozanimod NDA; Celgene's potential use of a priority review voucher for Ozanimod; and Celgene's receipt of an RTF letter from the FDA for the Ozanimod NDA.

25. Witness: Representative of Lead Plaintiff AMF

Address: C/O Kessler Topaz Meltzer & Check LLP

Live/By Videotaped Deposition: Live

Summary of Testimony: To the extent the Court denies Plaintiff's Motion to Bifurcate Trial into Two Phases, Plaintiff expects to call as a live witness a representative of Lead Plaintiff AMF to testify concerning AMF's transactions in Celgene common stock during the Class Period, including transactions by AMF Fonder AB (AMF Fonder"), which assigned its claims based on AMF Fonder's transactions in Celgene common during the Class Period stock to AMF.

B. On damages, plaintiff intends to call the following witnesses who will testify in accordance with the following summaries:

1. Witness: **David Tabak**

Address: C/O Kessler Topaz Meltzer & Check LLP

Live/By Videotaped Deposition: Live

Summary of Testimony: Dr. Tabak is an expert witness who will serve as Plaintiff's expert on loss causation and damages and will provide testimony that each of the alleged corrective disclosures resulted in losses to investors; describe a method for estimating investors' per-share losses and recoverable per-share damages; opine as to a reasonable estimate of investors' per-share

losses and recoverable per-share damages; and provide additional testimony relevant to materiality and reliance.

C. Defendants object to the following witnesses for the reasons stated:

1. Terrie Curran is a Defendant who will be testifying live and who was not a Celgene officer, director, managing agent, or designee under Rule 30(b)(6) or 31(a)(4) at the time of her deposition. Defendants object to Plaintiff's attempt to introduce her deposition testimony pursuant to Fed. R. Civ. P. 32(a)(3) as it will cause unfair prejudice, confuse the issues, mislead the jury, cause undue delay, waste time, or needlessly present cumulative evidence. *See* FED. R. CIV. P. 45; FED. R. EVID. 403, 802.

2. If Scott Smith testifies live, Defendants object to Plaintiff's attempt to introduce his deposition testimony as he is not a party and was not a Celgene officer, director, managing agent, or designee under Rule 30(b)(6) or 31(a)(4) at the time of his deposition. *See* FED. R. CIV. P. 32(a)(3).

3. Defendants object to Plaintiff's proposed "Document Reader" as it will cause unfair prejudice, confuse the issues, mislead the jury, cause undue delay, waste time, or needlessly present cumulative evidence. *See* FED. R. CIV. P. 45; FED. R. EVID. 403, 802.

VII. DEFENDANTS' WITNESSES (See instructions above).

A. Defendants intend to call the following witnesses who will testify in accordance with the following summaries:

1. Otezla Trial

1. Witness: **Representative of Lead Plaintiff AMF Tjänstepension AB**

Address: c/o Lead Counsel

Live/By Videotaped Deposition: Deposition

Summary of Testimony: Defendants expect to present deposition testimony pursuant to Fed. R. Civ. P. 32(a)(3) of the Representative of AMF regarding AMF's purchase of Celgene stock, including the timing, process and reason for its investment, AMF's experience and process for investing in public companies, the role of AMF's investment professionals and outside advisors, and the loss of evidence from personnel who had roles regarding AMF's investment decision-making.

2. Witness: **Terrie Curran**

Address: 100 Campus Drive

Suite 102

Florham Park, NJ 07932

Live/By Videotaped Deposition: Live

Summary of Testimony: Terrie Curran was President of Celgene's Inflammation & Immunology division, which included Otezla. Curran will testify about Otezla, including sales and other financial metrics regarding the product, forecasting future sales of Otezla, and that her statements regarding Otezla during Celgene's April and July 2017 quarterly earnings calls, that are the basis for Plaintiff's Otezla claims, were truthful.

3. Witness: **Scott A. Smith**

Address: Robert J. Coury Global Center

1000 Mylan Boulevard

Canonsburg, PA 15317

Live/By Videotaped Deposition: Deposition

Summary of Testimony: Scott Smith was President and Chief Operating Officer of Celgene. Smith will testify that Celgene's public disclosures regarding Otezla were truthful.

4. Witness: **Robert Tessarolo**

Address: Robert J. Coury Global Center

1000 Mylan Boulevard

Canonsburg, PA 15317

Live/By Videotaped Deposition: Deposition

Summary of Testimony: Robert Tessarolo was the Vice President and General Manager of U.S. Inflammation & Immunology at Celgene from September 2015 to March 2017. He will testify that Otezla sales and market share were growing rapidly during his time at Celgene; that he did not have concerns about Celgene's ability to meet sales and market share targets in 2017.

5. Witness: **Hunter Smith**

Address: 222 Berkeley Street

12th Floor

Boston, MA 02116

Live/By Videotaped Deposition: Deposition

Summary of Testimony: Hunter Smith was the Vice President of Finance at Celgene. Smith provided forecasts for Celgene's management related to Otezla's 2017 performance. Smith spoke directly with Terrie Curran and provided her with information related to maintaining the forecasted budget prior to the April 2017 earnings call. He will

testify that Curran's statements regarding Otezla during Celgene's April and July 2017 quarterly earnings calls, that are the basis for Plaintiff's Otezla claims, were truthful.

6. Witness: **Doug Bressette**

Address: 510-513 Walnut Street,

Suite 1350

Philadelphia, PA 19106

Live/By Videotaped Deposition: Deposition

Summary of Testimony: Doug Bressette was the Senior Director of Global Business Planning and Analysis (Inflammation & Immunology) at Celgene. He will testify that Celgene established the 2017 Otezla sales forecast based on a rigorous review of data and business analytics; early sales numbers in 2017 did not worry Celgene executives regarding the ability to meet year-end guidance; and that Curran's statements regarding Otezla during Celgene's April and July 2017 quarterly earnings calls, that are the basis for Plaintiff's Otezla claims, were truthful.

7. Witness: **Brian Reisetter, Ph.D.**

Address: c/o Defendants' Counsel

Live/By Videotaped Deposition: Live

Summary of Testimony: Brian Reisetter is an expert witness who will testify regarding the opinions disclosed in the report he provided pursuant to Federal Rule of Civil Procedure 26(a)(2)(B), including, but not limited to, his opinions that: Dr. Stomberg's opinions and analyses are flawed and unreliable, including because he makes erroneous inferences regarding the available data and evidence and mischaracterizes or subjectively interprets select market research; for its Otezla sales forecast, Celgene used forecast

methods that considered actual market data, and these methods were in line with the academic literature and industry practice; and Celgene had substantial opportunities to increase market sales of Otezla during the relevant period.

8. Witness: **Dr. Gary Solomon**

Address: c/o Defendants' Counsel

Live/By Videotaped Deposition: Live

Summary of Testimony: Dr. Gary Solomon is an expert witness who will testify regarding the opinions disclosed in the report he provided pursuant to Federal Rule of Civil Procedure 26(a)(2)(B), including, but not limited to, his opinions that: Otezla is useful and safe for treating a selected subset of patients with psoriasis and/or psoriatic arthritis; and there were numerous studies showing its safety and efficacy during the relevant period.

9. Witness: **Paul Gompers**

Address: c/o Defendants' Counsel

Live/By Videotaped Deposition: Live

Summary of Testimony: Paul Gompers is an expert witness who will testify regarding any of his opinions disclosed in the report he provided pursuant to Federal Rule of Civil Procedure 26(a)(2)(B), including, but not limited to, his opinions that: Plaintiff's expert, David Tabak's causation and damages opinions are unreliable and incorrect because he ignored relevant information and made improper assumptions.

10. Defendants reserve the right to call any of the witnesses that Plaintiff has identified in this Joint Pretrial Order.

2. Ozanimod Trial

1. Witness: **Representative of AMF Fonder AB**

Address: c/o Lead Counsel

Live/By Videotaped Deposition: Deposition

Summary of Testimony: To the extent the Court allows AMF to amend its complaint to assert the purported claim that was assigned to it by AMF Fonder, to continue to act as class representative for the Ozanimod claims and/or to present evidence of AMF's assignment of AMF Fonder's claim to AMF, Defendants expect to present deposition testimony pursuant to Fed. R. Civ. P. 32(a)(3) of a Representative from AMF Fonder regarding AMF Fonder's purchase of Celgene stock, including the timing, process and reason for its investment, AMF Fonder's experience and process for investing in public companies, the role of AMF Fonder's investment professionals and outside advisors, and its assignment of its claim to AMF.

2. Witness: **Representative of Lead Plaintiff AMF Tjänstepension AB**

Address: c/o Lead Counsel

Live/By Videotaped Deposition: Deposition

Summary of Testimony: To the extent the Court allows AMF to amend its complaint to assert the claim that was assigned to it by AMF Fonder, to continue to act as class representative for the Ozanimod claims and/or to present evidence of AMF's assignment of AMF Fonder's claim to AMF, Defendants expect to present deposition testimony pursuant to Fed. R. Civ. P. 32(a)(3) of the Representative of AMF regarding AMF's lack of purchase of Celgene stock following any of the October 2017 Ozanimod challenged statements and AMF Fonder's assignment of its claim to AMF.

3. Witness: **Terrie Curran**

Address: c/o Defendants' Counsel

Live/By Videotaped Deposition: Live

Summary of Testimony: Terrie Curran was President of Celgene's Inflammation & Immunology division, which included Ozanimod. Curran will testify that she relied on the accuracy of her team regarding the accuracy of Celgene's public disclosures concerning Ozanimod. Curran will testify that she relied on her team regarding whether the Ozanimod NDA was ready for submission to the FDA at the end of 2017, that she was told the Ozanimod NDA was ready, and that she was shocked when Celgene received an RTF from the FDA.

4. Witness: **Scott A. Smith**

Address: Robert J. Coury Global Center

1000 Mylan Boulevard

Canonsburg, PA 15317

Live/By Videotaped Deposition: Deposition (unless available to testify Live)

Summary of Testimony: Scott Smith was President and Chief Operating Officer of Celgene. S. Smith will testify that he relied on his team regarding the accuracy of Celgene's public disclosures concerning Ozanimod. He will also testify that he relied on information he received in updates from I&I leadership as well as members of the Ozanimod NDA team located in San Diego regarding whether the Ozanimod NDA was ready for submission at the end of 2017. S. Smith will also testify that he was informed by Backstrom in December 2017 that the Ozanimod NDA was ready to be submitted to the FDA, and that he was shocked when Celgene received an RTF.

5. Witness: **Philippe Martin**

Address: c/o Defendants' Counsel

Live/By Videotaped Deposition: Live

Summary of Testimony: Philippe Martin was the Vice President of Leadership & Project Management and a Managing Director at Celgene-Receptos. In that role, Martin supervised Saillot, who was the Ozanimod MS Team lead. Martin will testify that he had regular discussions with the Ozanimod MS Team regarding its plan for addressing the Metabolite, that he believed the NDA appropriately addressed the FDA's feedback on the Ozanimod Briefing Book, that he believed the Ozanimod NDA would be accepted by the FDA, and that he did not expect to receive an RTF.

6. Witness: **Jay T. Backstrom**

Address: 301 Binney Street

3rd Floor

Cambridge, MA 02142

Live/By Videotaped Deposition: Deposition

Summary of Testimony: Jay Backstrom was Celgene's Chief Medical Officer who reported to Scott Smith. Backstrom will testify that he reviewed for accuracy Celgene's statements to investors about the status of the Ozanimod NDA, that he believed the NDA appropriately addressed the FDA's feedback on the Ozanimod Briefing Book, that he was part of the "executive committee that look[ed] at [the ozanimod NDA] in general" and "ma[de] a decision" about whether it was "ready to submit," and that he told Curran and S. Smith that the Ozanimod NDA was "ready to go."

7. Witness: **Jean-Louis Saillot**

Address: 450 Santa Dominga

Solana Beach, CA 92075

Live/By Videotaped Deposition: Deposition

Summary of Testimony: Jean-Louis Saillot was the Vice President of Project Leadership, Regulatory Affairs and Clinical Pharmacology at Receptos. In that role, he led the Ozanimod MS Team in charge of the NDA Submission. Saillot will testify that following the discovery of the Metabolite, the Ozanimod MS Team worked hard to adequately characterize it for the NDA, that the Ozanimod MS Team put together a "quality submission" that addressed the FDA's feedback on the Ozanimod Briefing Book, and that he was shocked by the FDA's RTF.

8. Witness: **Susan Meier-Davis**

Address: 450 Santa Dominga

Solana Beach, CA 92075

Live/By Videotaped Deposition: Deposition

Summary of Testimony: Susan Meier-Davis was the Senior Director in Pre-Clinical Sciences at Receptos. Meier-Davis will testify that she was responsible for oversight of the nonclinical pharmacology section of the Ozanimod NDA, and in that role, she worked closely with Celgene's consultants, Dr. Jacobson-Kram and Dr. Marcie Wood. Meier-Davis will testify that was "shocked" when Celgene received the RTF because "when you read their reason for the non-clinical insufficiency" it "seemed fairly minor."

9. Witness: **Jonathan Tran**

Address: 13520 Evening Creek Drive North

Suite 430

San Diego, CA 92128

Live/By Videotaped Deposition: Deposition

Summary of Testimony: Jonathan Tran was the Executive Director of Clinical Pharmacology at Receptos. Tran will testify that he was responsible for oversight of the clinical pharmacology section of the Ozanimod NDA, and in that role, he worked closely with Celgene's consultant, Dr. Lawrence Lesko. Tran will testify that he and his team worked hard to address the FDA's feedback on the Ozanimod Briefing Book, and in particular, its request that Celgene submit a "full" clinical study report of RPC01-1001 as opposed to an abbreviated one, prior to the NDA submission. He will also testify that he did not think the NDA submission would receive an RTF.

10. Witness: **David Kao**

Address: Torrey Pines Science Park

11025 North Torrey Pines Road

Suite 140

La Jolla, CA 92037

Live/By Videotaped Deposition: Deposition

Summary of Testimony: David Kao was Senior Director of Regulatory Affairs at Receptos. Kao will testify that he was the global regulatory lead for all aspects of drug development for the products to which he was assigned, including Ozanimod. In that role, he advised the Ozanimod MS Team on the FDA's guidance regarding issues raised as a result of the discovery of the Metabolite, to the extent it was available for this unique situation, but that FDA guidance is not mandatory.

11. Witness: **Gerlee Thomas**

Address: 11085 Torreyana Rd

San Diego, CA 92121

Live/By Videotaped Deposition: Deposition

Summary of Testimony: Gerlee Thomas was Director of Regulatory Affairs at Receptos, reporting to David Kao. She will testify that in that role, she was responsible for working with the Ozanimod MS Team to compile the information that needed to be included in the NDA submission.

12. Witness: **David Wilson**

Address: 3115 Merryfield Row

Suite 120

San Diego, CA 92121

Live/By Videotaped Deposition: Deposition

Summary of Testimony: David Wilson was clinical bioanalytical lead at Celgene, reporting to Jonathan Tran. He will testify regarding the FDA's non-binding guidance for long term stability data as it relates to the Metabolite and the Ozanimod NDA submission.

13. Witness: **Maria Palmisano**

Address: c/o Defendants' Counsel

Live/By Videotaped Deposition: Live

Summary of Testimony: Maria Palmisano was Vice President and head of Clinical Pharmacology at Celgene. She will testify that in that role, she commented on the Ozanimod Briefing Book and other aspects of the clinical pharmacology section of the Ozanimod NDA submission related to the Metabolite, and never advised that the NDA should not be submitted.

14. Witness: **Gondi Kumar**

Address: c/o Defendants' Counsel

Live/By Videotaped Deposition: Live

Summary of Testimony: Gondi Kumar was Vice President and head of Nonclinical Development at Celgene. He will testify that in that role, he commented on the Ozanimod Briefing Book and other aspects of the nonclinical pharmacology and toxicology section of the Ozanimod NDA submission related to the Metabolite, and never advised that the NDA should not be submitted.

15. Witness: **Russell Katz**

Address: 2 North Tamiami Trail

Suite 308

Sarasota, FL 34236

Live/By Videotaped Deposition: Live

Summary of Testimony: Russell Katz is the former Director for the Division of Neurology Products at the FDA. He will testify regarding his consultation for the Ozanimod MS Team and its plan for addressing the Metabolite in its Ozanimod NDA submission.

16. Witness: **Marcie Wood**

Address: 23501 Cinco Ranch Blvd

Suite H210

Katy, TX 77494

Live/By Videotaped Deposition: Live

Summary of Testimony: Marcie Wood was a pharmacology/ toxicology supervisor and reviewer in the Division of Pulmonary, Allergy, and Rheumatology Products at the FDA. She will testify regarding her consultation for the Ozanimod MS Team and its plan

for addressing the Metabolite in the nonclinical pharmacology/toxicology sections of the Ozanimod NDA submission.

17. Witness: **David Jacobson-Kram**

Address: 1129 20th St NW, Suite 600

Washington DC, 20036

Live/By Videotaped Deposition: Deposition

Summary of Testimony: David Jacobson-Kram is the former Director for the Executive Cardinogenesis Assessment Committee at the FDA. He will testify regarding his consultation for the Ozanimod MS Team and its plan for addressing the Metabolite in the nonclinical pharmacology/toxicology sections of the Ozanimod NDA submission.

18. Witness: **Lawrence J. Lesko**

Address: 6550 Sanger RD OFC 464

Orlando, FL 32827

Live/By Videotaped Deposition: Deposition

Summary of Testimony: Lawrence Lesko is the former Director of the Office of Clinical Pharmacology at the FDA. He will testify regarding his consultation for the Ozanimod MS Team and its plan for addressing the Metabolite in the clinical pharmacology section of the Ozanimod NDA submission.

19. Witness: **Dr. William David McGuinn**

Address: c/o Defendants' Counsel

Live/By Videotaped Deposition: Live

Summary of Testimony: Dr. William David McGuinn is an expert witness who will testify regarding any of his opinions disclosed in the report he provided pursuant to Federal

Rule of Civil Procedure 26(a)(2)(B), including, but not limited to, his opinions that: the opinions of Plaintiff's expert, Professor Guengerich, are inadequate and that Professor Guengerich does not have the relevant experience or expertise to offer certain of his opinions; the FDA's guidance is non-binding; there are no clear industry standards, customs, and practices for characterizing disproportionate metabolites following two successful Phase III clinical trials; the data presented with Celgene's Ozanimod NDA submission was sufficient for purposes of a regulatory safety assessment; the FDA should have found Celgene's data sufficient; and there was a reasonable likelihood that FDA could have approved the original ozanimod NDA.

20. Witness: **Dr. James H. Sherry**

Address: c/o Defendants' Counsel

Live/By Videotaped Deposition: Live

Summary of Testimony: Dr. James H. Sherry is an expert witness who will testify regarding any of his opinions disclosed in the report he provided pursuant to Federal Rule of Civil Procedure 26(a)(2)(B), including, but not limited to, his opinions that: Dr. Fleischer mischaracterizes FDA guidance's meaning and authority, ignores other resources a drug developer consults in preparing an NDA, and, as a result, overstates the risk that a drug developer might receive adverse action; FDA regulations and statutes, which are the only sources of binding authority, do not require "full study reports" to include long-term stability ("LTS") data for all samples; Celgene submitted study reports that were consistent with the requirements of the FDA regulations and suggestions of the FDA guidance; Celgene was reasonable in believing that the FDA would file the NDA because Celgene consulted with former decision-makers at the FDA; the FDA's pre-NDA comments to

Celgene in November 2017 did not state how much LTS data Celgene needed to submit, and that, if it did not, Celgene would receive an RTF; Ozanimod had the potential to meet an unmet need in the treatment of MS; and the FDA could have required Celgene to submit additional LTS data as a post-marketing requirement, or handled the unknown characterization of the Metabolite with labeling; Dr. Guengerich is incorrect in stating that the results of a study are necessarily unreliable if LTS data is lacking; and FDA guidance is ambiguous as to whether a pharmaceutical developer must provide LTS data for all samples and all analytes in a study, and no statute or regulation contains such a requirement.

21. Witness: **Paul Gompers**

Address: c/o Defendants' Counsel

Live/By Videotaped Deposition: Live

Summary of Testimony: Paul Gompers is an expert witness who will testify regarding any of his opinions disclosed in the report he provided pursuant to Federal Rule of Civil Procedure 26(a)(2)(B), including, but not limited to, his opinions that: Plaintiff's expert, David Tabak's causation and damages opinions are unreliable and incorrect because he ignored relevant information and made improper assumptions.

22. Defendants reserve the right to call any of the witnesses that Plaintiff has identified in this Joint Pretrial Order.

B. Plaintiff objects to the following witnesses for the reasons stated:

1. Plaintiff objects to Defendants' presentation of any deposition testimony by AMF's corporate designee or AMF Fonder's corporate designee at the Phase One trial, which should be limited to issues of Class-wide liability and per-share damages, as such testimony will cause unfair prejudice, confuse the issues, and mislead the jury. Fed. R. Evid. 403; *see* Plaintiff's Statement on

Bifurcation, *infra* Section XIX; Plaintiff's Motion to Bifurcate Trial into Two Phases. Additionally, Plaintiff objects to Defendants' presentation of any testimony regarding AMF's alleged loss of evidence from personnel who had roles regarding AMF's investment decision-making. Such testimony is not relevant to any issue to be decided at the Phase One or Phase Two trial, and will only be offered for the improper purpose of suggesting that AMF spoliated relevant evidence. Fed. R. Evid. 401, 403. The Court has already ruled that based on AMF's Rule 30(b)(6) testimony, AMF did not spoliate evidence. *See* D.E. 114 at 11-12 ("Defendants fail to demonstrate that Plaintiff acted with the intent to deprive Defendants of [electronically stored information]" and "outside of speculation, Defendants fail to plausibly identify any relevant information that was likely destroyed").

VIII. DEPOSITION DESIGNATIONS

1. Plaintiff's Deposition Designations and Defendants' objections are listed in Appendix A. Defendants' Deposition Designations and Plaintiff's objections and counter-designations are listed in Appendix B.

2. The parties have designated testimony for witnesses they will or may call at trial based on their current understanding of the issues to be tried, whether a witness is within the subpoena power of the Court or is otherwise available for trial, or whether the Court will permit the witness's deposition to be introduced pursuant to Federal Rule of Civil Procedure 32. Both parties reserve to the right to later designate testimony prior to trial if it is determined that a witness currently expected to testify live is unavailable, or to call live a witness that is currently expected to testify by deposition. Both parties further reserve the right to revise or amend their deposition designations as the parties continue to meet and confer regarding pre-trial matters and submit and receive decisions from the Court related to pending or anticipated motions.

3. Because Defendants' Deposition Designations do not specify which of their designations are affirmative designations and which are counter-designations, Plaintiff's objections to Defendants' designations for witnesses for whom Plaintiff has designated testimony assume that all of Defendants' designations are counter-designations intended to be presented during Plaintiff's case in chief. Defendants have indicated they intend to call many of the same witnesses as Plaintiff, and Defendants reserve the right to present the deposition testimony they have designated during Plaintiff's case in chief or as part of Defendants' case. The parties will continue to confer about the deposition testimony that each will present during trial, as well as the manner and timing of the presentation of such testimony, as they prepare for trial.

IX. EXPERT WITNESSES (No opposing counsel shall be permitted to question the expert's qualifications unless the basis of an objection is set forth herein).

A. Plaintiff's expert witnesses are:

1. Chris Stomberg, Ph.D.

2. David I. Tabak, Ph.D.

3. Frederick Peter Guengerich, Ph.D.

4. Nicholas M. Fleischer, R.Ph., Ph.D.

5. Simon M. Helfgott, M.D.

B. Defendants' objections to the qualifications of plaintiff's experts are:

Defendants anticipate filing the following motions to limit or preclude portions of Plaintiffs' experts' testimony.

1. Chris Stomberg, Ph.D.

a. Motion to exclude Stomberg's testimony entirely on the basis that he lacks relevant experience forecasting expected pharmaceutical revenues.

b. Motion to preclude Stomberg's opinion that Otezla's growth was expected to stagnate in 2017 based on a Bass model, which has limited applicability to pharmaceutical products according to the sources Stomberg himself cites.

c. Motion to preclude Stomberg's opinion about the state of mind of Celgene and/or its executives, including that "Celgene was concerned" about sales losses, "there was concern that Celgene might lose business," that Otezla's sales performance was "far below expectations," and that Celgene's "internal analyses and communications" "suggested" its 2017 budget was unattainable.

d. Motion to preclude Stomberg's opinions about the achievability of Otezla sales projections and the strength of Otezla performance metrics using evidence that post-dates Curran's statements.

2. David I. Tabak, Ph.D.

a. Motion to preclude legal conclusions concerning materiality of information at issue.

b. Motion to preclude Tabak's opinion concerning Otezla inflation as unreliable because: (1) his disaggregation methodology fails to account for confounding information regarding revisions to 2020 revenue guidance; and (2) he arbitrarily, not based on reliable principles and methods, chooses a method (the four-week model) that fit his pre-determined outcome.

c. Motion to preclude Tabak's opinion concerning Ozanimod inflation as unreliable because his methodology improperly assumes that Celgene did not disclose the information in the Receptos posters to the public when, in fact, that information was available to the public before Morgan Stanley's report.

3. Frederick Peter Guengerich, Ph.D.

a. Motion to exclude Guengerich's testimony entirely because he has not worked at the FDA or a pharmaceutical company. His academic scholarship also does not address regulatory approval of new drugs or characterization of metabolites discovered late in development.

b. Motion to preclude Guengerich's opinion concerning the clinical pharmacology basis for the RTF, long-term stability, as Guengerich is not a clinical pharmacologist.

c. Motion to preclude Guengerich's opinion as to the sufficiency of Celgene's NDA submission. While he claims to base his opinions on "industry customs," he does not identify those customs, and there are no "industry customs" for the late-stage discovery of a major metabolite in connection with positive Phase III trials.

d. Motion to preclude Guengerich's opinion that FDA guidance is required/binding.

4. Nicholas M. Fleischer, R.Ph., Ph.D.

a. Motion to preclude Fleischer's opinions about the sufficiency of Celgene's NDA submission entirely, because while he claims to base his opinions on "industry customs," he does not identify those customs, and there are no such "industry customs" for the late-stage discovery of a major metabolite in connection with positive Phase III trials. He also has limited relevant professional experience: he worked primarily on ANDA's, never had authority to issue an RTF, and his FDA experience was not specific to neurology products.

b. Motion to preclude Fleischer's opinions that FDA guidance is required/binding.

c. Motion to preclude Fleischer's opinions based on: (1) CFR provisions as evidence of what Celgene should have done to avoid an RTF when those provisions do not explicitly concern long-term stability data and (2) claims that Celgene was required to submit more LTS than what the FDA ultimately accepted.

5. Simon M. Helfgott, M.D

a. Motion to exclude Helfgott's testimony entirely as irrelevant, because Curran's alleged misstatements do not concern Otezla's efficacy/safety, and we could argue his opinions are likely to confuse the issues / mislead the jury.

b. Motion to exclude Helfgott's opinion as to the state of mind of "other practitioners during the Class Period" and their purported conclusions "that Otezla was an inferior treatment option."

c. Motion to exclude Helfgott's opinion as to the state of mind of physicians and patients, including opinions that Otezla's oral route of administration is not a dispositive selling point for the "vast majority" of patients.

d. Motion to exclude Helfgott's opinion that the lack of laboratory monitoring for Otezla offers "little concrete benefit" for "most patients" because Helfgott speculates that "most physicians are likely" to order lab work anyway.

e. Motion to exclude Helfgott's opinion that Otezla is a "prohibitively expensive medication."

C. Defendants' expert witnesses are:

1. Dr. W. David McGuinn

2. Brian Reisetter, Ph.D.

3. Paul Gompers, Ph.D.

4. Dr. James H. Sherry

5. Dr. Gary Solomon

D. Plaintiff's objections to the qualifications of Defendants' experts are:

Plaintiff anticipates filing the following motions to limit or preclude portions of Defendants' experts' testimony.

1. Motion to preclude Dr. Gompers from providing multiple improper opinions, including:

a. That the change to Otezla's 2020 guidance is "not at issue" in this case, which is a pure legal question that the Court already decided in Plaintiff's favor and also ignores the operative complaint.

b. Dr. Gompers' "illustrative" artificial inflation estimate for the Otezla-related corrective disclosure because he conceded that he did not perform an event study or any methodologically sound damages analysis.

c. Dr. Gompers' related opinion that the Otezla and Ozanimod price declines "could have" been caused by other factors.

d. Dr. Gompers' opinion that Dr. Tabak was required to construct and identify a hypothetical "but-for" disclosure that would have revealed the fraud, which is not a requirement to prove loss causation in the Third Circuit.

e. Dr. Gompers' testimony regarding the so-called materialization of "known" risks, which misstates the law and is otherwise unreliable.

f. Dr. Gompers' opinion that the "market was aware" of certain information, which is improper state of mind testimony, improperly cherry-picks one or two analyst

reports to represent the market as a whole, and otherwise is not reliant on any expert analysis.

2. Motion to preclude Dr. Solomon from offering the following opinions:

a. Any opinion as to the relevant market of treatment options for psoriasis or psoriatic arthritis, which he conceded he did not examine;

b. Any opinion that Otezla was "safer" than any of biologic therapies;

c. Testimony or opinions regarding evidence that is irrelevant and whose probative value is substantially outweighed by a danger of unfair prejudice, confusing the issues, and misleading the jury, including:

i. The price Amgen paid for Otezla, as well as Amgen's assessment of the value Otezla added to its portfolio;

ii. Amgen's post-acquisition forecasts and sales;

iii. Testimony regarding increased Otezla sales during the Covid-19 pandemic or regarding Otezla's purported benefits in a pandemic; and

iv. Testimony concerning any new medications that came into existence after the end of the Class Period and that do not concern or relate to information in Defendants' possession during the Class Period or statements made by Defendants during the Class Period.

3. Motion to preclude Dr. Reisetter from offering any opinion regarding the state of mind of any party.

4. Motion to preclude Dr. Sherry from opining on the state of mind or motive of Defendants and third parties, including the FDA and external consultants; from providing an improper legal opinion; from testifying that the FDA should have acted differently instead of

issuing the RTF; from testifying that the FDA's post-Class Period approval of the rNDA demonstrates that there were no deficiencies in the original NDA submission; and from offering any opinion to suggest that Defendants reasonably relied upon the advice of external experts in deciding to submit the NDA without sufficient data

5. Motion to preclude Dr. McGuinn from opining on the state of mind or motive of Defendants and third parties, including the FDA and external consultants; from providing an improper legal opinion; from improperly vouching for Dr. Jacobson-Kram or providing any fact testimony regarding his service with Dr. Jacobson-Kram at the FDA; from testifying that the FDA should have acted differently instead of issuing the RTF; from testifying that the FDA's post-Class Period approval of the rNDA demonstrates that there were no deficiencies in the original NDA submission; and from offering any opinion to suggest that Defendants reasonably relied upon the advice of external experts in deciding to submit the NDA without sufficient data.

X. PLAINTIFF'S EXHIBITS (Except for exhibits the need for which could not reasonably have been foreseen or which are used solely for impeachment purposes, only the exhibits set forth on the exhibit list attached hereto may be introduced at trial. Any objection to an exhibit, and the reason for said objection, must be set forth below or it shall be deemed waived. All parties hereby agree that it will not be necessary to bring in the custodian of any exhibit as to which no such objection is made).

A. Plaintiff intends to introduce into evidence the exhibits listed on the attached exhibit list (list by number with a description of each):

1. *See* Appendix C.

2. Plaintiff has included on its Exhibit List exhibits related to AMF's transactions in Celgene common stock during the Class Period, including transactions by AMF's subsidiary, AMF Fonder, which assigned its claims based on AMF Fonder's transactions in Celgene common stock to AMF. *See* Appendix C, Exhibits 872-874. Inclusion of these exhibits is not intended as a waiver of any arguments that other evidence related to AMF should be precluded from the Phase One trial. *See* Plaintiff's Motion to Bifurcate Trial into Two Phases; Plaintiff's Statement on Bifurcation,

infra Section XIX. To the extent the Court denies Plaintiff's Motion to Bifurcate Trial into Two Phases, Plaintiff reserves the right to supplement its Exhibit List to include additional evidence related to its transactions in Celgene common stock during the Class Period.

B. Defendants object to the introduction of plaintiff's exhibits (set forth number of an exhibit and grounds for objection):

1. *See* Appendix C.

2. Defendants reserve the right to object to any exhibits that Plaintiff declined to include in its initial exhibit list as a result of its anticipated bifurcation motion, but later attempts to add to the exhibit list for trial.

XI. DEFENDANTS' EXHIBITS (See instructions above).

A. Defendants intend to introduce into evidence the exhibits listed on the attached exhibit list (list by number with a description of each):

1. *See* Appendix D.

2. Defendants reserve the right to supplement its exhibit list, including to respond to attempts by Plaintiff to add trial exhibits or to add exhibits based on any discovery that occurs following the submission of this Joint Pretrial Order (including but not limited to discovery regarding or relating to AMF Fonder's alleged purchase of Celgene securities and purported assignment of its claim in this action to Plaintiff).

B. Plaintiff objects to the introduction of Defendant's exhibits (set forth number of exhibit and grounds for objection):

1. *See* Appendix D.

(Copies of exhibits are to be made for opposing counsel, and a bench book of exhibits is to be delivered to the Judge at the start of trial. If counsel desires to display exhibits to the jury, sufficient copies should be available to provide each juror with a copy; alternatively, enlarged photographic or projected copies may be used).

XII. PLAINTIFF'S LEGAL ISSUES

1. Whether Defendants violated Sections 10(b) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder. The elements of Plaintiff's and the certified Class's Section 10(b) Claim are: (1) Defendants made an untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; (2) Defendants' misstatement or omission of a material fact was made in connection with the purchase or sale of Celgene common stock; (3) Defendants used an instrumentality of interstate commerce or a facility of a national security exchange in connection with their misstatement or omission of a material fact; (4) Defendants acted with scienter, i.e., knowingly or recklessly; (5) Plaintiff and the Class relied on Defendants' misstatement or omission of a material fact in purchasing Celgene common stock; and (5) Defendants' misstatement or omission of a material fact caused Plaintiff and the Class to suffer damages. *See* 15 U.S.C. § 78j(b); 17 C.F.R. § 240.10b-5.

XIII. DEFENDANTS' LEGAL ISSUES

1. Whether there is sufficient evidence for Plaintiff to sustain each required element of its claims under 10(b) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder.

2. Whether AMF has standing to pursue claims related to the alleged statements and omissions regarding Ozanimod.

3. Whether AMF can adequately represent a class of Celgene investors with respect to claims related to the alleged statements and omissions regarding Ozanimod, and relatedly whether the current Class must be decertified.

4. Whether certain of Plaintiff's alleged misstatements or omissions are not actionable as a matter of law because they are subject to the PSLRA's safe harbor provision, *see* 15 U.S.C. § 78u-5(c).

5. Whether any individual members of a class of Celgene investors can establish reliance on any alleged misstatement or omission.

6. Whether Plaintiff can apply the corporate scienter doctrine to Celgene through Terrie Curran and Scott Smith.

XIV. CHOICE OF LAW: (If there is any issue as to what state's law is applicable to any count of the complaint, set forth the choice of law question. This issue shall be separately briefed in accordance with an order to be entered herewith).

1. N/A

XV. MISCELLANEOUS (Set forth any other matters which require action by, or should be brought to the attention of the Court).

1. N/A

XVI. JURY TRIALS - Not later than 30 days before trial:

1. Each side shall submit to the Judge and to opposing counsel a trial brief or memorandum in accordance with Local Civil Rule 7.2B, with citations to authorities and arguments in support of its position on all disputed issues of law. In the event a brief shall not be filed, the delinquent party's complaint or defense may be stricken.

2. Counsel for each party shall submit to the Judge, with a copy to opposing counsel, written requests for instructions to the jury. Supplemental requests for instructions may be submitted at any time prior to argument to the jury. All requests for instructions shall be plainly marked with the name and number of the case, shall contain citations of supporting authorities, if any, and shall designate the party submitting same. In the case of multiple requests by a party, these shall be numbered in sequence and each request shall be on a separate sheet of paper.

3. Joint proposed verdict form/special interrogatories are to be submitted to the trial judge.

4. Proposed voir dire are to be submitted to the trial judge.

The parties agree to exchange written requests for instructions to the jury, proposed verdict form/special interrogatories and proposed voir dire at least 14 days in advance of the foregoing submissions, and agree to meet and confer prior to the foregoing submissions in an effort to reach agreement and narrow the scope of any disputes.

XVII. NON-JURY TRIALS - Not later than N/A.

1. Each side shall submit to the Judge and opposing counsel a trial brief or memorandum in accordance with Local Civil Rule 7.2B with citation to authorities and arguments in support of its position on all disputed issues of law. In the event a brief shall not be filed, the delinquent party's complaint or defense may be stricken.

2. Each side shall submit to the Judge and other counsel proposed written findings of fact and conclusions of law. There is reserved to counsel the right to submit additional proposed findings of fact and conclusions of law during the course of the trial on those matters that cannot reasonably be anticipated.

XVIII. TRIAL COUNSEL (List the names of trial counsel for all parties).

Counsel for Plaintiff AMF and the Certified Class

KESSLER TOPAZ MELTZER & CHECK, LLP
Matthew L. Mustokoff
Margaret E. Mazzeo
Jamie M. McCall
Nathan A. Hasiuk

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Robert F. Kravetz
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Counsel for Defendants

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Kevin M. McDonough

JONES DAY
Robert C. Micheletto
Nidhi Yadava
Rajeev Muttreja
Sarah D. Efronson

GIBBONS P.C.
Lawrence S. Lustberg
Kate E. Janukowicz

XIX. BIFURCATION (Where appropriate, the issues relating to liability shall be severed and tried to verdict. Thereafter, all issues relating to damages will be tried).

1. Plaintiff's Statement on Bifurcation

Plaintiff submits that the Court should bifurcate the trial into two phases—one that addresses common class-wide issues (including Defendants' liability and the measure of class-wide damages) (Phase One), and, if necessary, a second phase that addresses class member-specific individualized issues (Phase Two). Under this bifurcated structure, all evidence and argument on individualized issues, including those concerning Plaintiff and its transactions in Celgene common stock, would be excluded from Phase One—in accord with the overwhelming majority of courts to have presided over securities class action trials. *See, e.g.*, *Sjunde AP-Fonden v. Gen. Elec. Co.*, _ F. Supp. 3d _, 2024 WL 1208778, at *2 (S.D.N.Y. Mar. 21, 2024) ("[T]he trial will be bifurcated, with a Phase One limited to class-wide issues concerning liability and damages; and, only if necessary, a Phase Two addressing individual issues, including class member damages and any individual issues concerning reliance of both Class Representatives and other class members"); *In re Under Armor Sec. Litig.*, 2024 WL 2230177, at *1 (D. Md. May 16, 2024) ("[T]he trial will be bifurcated, with Phase One focusing solely on common, class-wide issues concerning liability and damages; and, if necessary, a Phase Two addressing issues specific to individual class members... [as] this approach advances the purposes of Rule 42(b)—it is more convenient, minimizes prejudice and risk of juror confusion, and is likely more efficient."); *Baker v. SeaWorld Ent., Inc.*, 2020 WL 241441, at *1 (S.D. Cal. Jan. 16, 2020) (bifurcating "trial into two phases—one for class-wide questions of Defendants' liability and the measure of damages (Phase One), and a second for Class member-specific individual issues (Phase Two)," holding "bifurcation promotes judicial economy and avoids prejudice" under Rule 42(b)); *Smilovits v. First*

Solar, Inc., 2019 WL 6698199, at *7 (D. Ariz. Dec. 9, 2019) ("The purpose of this trial is to resolve class-wide issues. Individual issues, such as Plaintiffs' possible individual lack of reliance on the market, must be addressed after the class trial."); *In re Facebook, Inc. IPO Sec. & Deriv. Litig.*, 312 F.R.D. 332, 351 (S.D.N.Y. 2015) (bifurcation "is the most efficient way to manage both the predominant common questions and the individualized questions... without overwhelming the common adjudication with individualized issues and vice versa"); *In re Vivendi Universal, S.A. Sec. Litig.*, 765 F. Supp. 2d 512, 584-85, 585 n.63 (S.D.N.Y. 2011), *aff'd*, 838 F.3d 223 (2d Cir. 2016) ("courts in securities fraud actions have consistently recognized that issues of individual reliance can and should be addressed after a class-wide trial, through separate jury trials if necessary"); *In re WorldCom, Inc. Sec. Litig.*, 2005 WL 408137, at *1 (S.D.N.Y. Feb. 22, 2005) (bifurcating trial of class-wide issues from subsequent one of "individualized knowledge, reliance, and damages issues"); *In re ICN/Viratek Sec. Litig.*, 1996 WL 34448146, at *1 (S.D.N.Y. July 15, 1996) ("[B]ifurcation of the jury trial in this action into two trials, to separately address class-wide issues and individual reliance issues, is proper"); *Waters v. Int'l Precious Metals Corp.*, 172 F.R.D. 479, 510 (S.D. Fla. 1996) (structuring trial to first resolve class-wide issues, then resolve individual issues); *see also In re Vesta Ins. Grp. Inc. Sec. Litig.*, Case No. 98-cv-01407, ECF No. 459 (N.D. Ala. Aug. 20, 2008) (precluding evidence and argument concerning individual reliance during class-wide proceeding).

Plaintiff intends to file a bifurcation motion following submission of this Final Pretrial Order.

2. Defendants' Statement on Bifurcation

Defendants submit that the Court should bifurcate the case such that there are two trials (one for the claims related to Otezla, and one for its claims related to Ozanimod) before two separate juries, for the reasons stated in Defendants' Memorandum Of Law In Support Of

Defendants' Motion To Bifurcate Trial, *see* Dkt. No. 352, and their Reply In Support Of Defendants' Motion To Bifurcate Trial, due to be filed on December 11, 2024.

Defendants reserve the right to oppose Plaintiff's bifurcation motion because, among other reasons, Plaintiff's Ozanimod claims can no longer proceed on a class-wide basis. *See*, *supra*, Section II.B. Further, Defendants intend to oppose any request by Plaintiff that evidence and argument concerning Plaintiff and its transactions in Celgene securities and/or AMF Fonder and its transactions in Celgene securities be excluded from any liability phase of trial.

Defendants agree that bifurcating the trial in this case with respect to issues *uniquely impacting absent class members* is necessary to promote judicial economy and the orderly presentation of certain issues. But excluding evidence or testimony regarding Plaintiff and/or AMF Fonder from the liability phases of trial would result in the exclusion of relevant evidence, unduly prejudice Defendants, and be contrary to efficient, sound trial management. Evidence regarding Plaintiff's and/or AMF Fonder's purchases of Celgene stock is relevant to multiple liability and damages issues the jury must decide and can be easily presented to the jury through their testimony. In one of the few federal securities class actions to be tried to verdict in the last decade, *Hsu v. Puma Biotechnology, Inc.*, the court refused to bifurcate evidence related to the class representative, including evidence regarding the class representative's purchase in Puma stock, finding it was relevant to plaintiff's assertion of the class-wide fraud-on-the-market presumption of reliance and defendant's ability to rebut that presumption. *See* 2021 WL 2644100, at *1-2 (C.D. Cal. June 11, 2021). And more recently, in a federal securities class action that proceeded to trial, but for which the jury has not yet reached a verdict, the court denied the class representative's attempt to bifurcate evidence of its own transactions in the relevant stock from the liability phase of trial after defendants argued such testimony was relevant to materiality and

reliance. *See* Tr. of Proceedings in *In re: Alta Mesa Resources, Inc., Securities Litigation*, 19-CV-957 (S.D. Tex. Nov. 6, 2024) at 26:16-19. Finally, Defendants submit that Plaintiff's cases cited herein do not concern bifurcation of trial at all or address high-level questions of whether or when a trial should be bifurcated not specific to the issue Plaintiff seeks to litigate here, are inapplicable because the parties' consented to bifurcation, and/or turn on unique facts and circumstances not present here.

XX. ESTIMATED LENGTH OF TRIAL

Plaintiff estimates that it will take approximately 10 trial days to present its case-in-chief and rebuttal case on issues of Class-wide liability and inflation-per-share damages, not including jury selection. As explained above in Plaintiff's statement on bifurcation, issues pertaining to individual Class members should be determined in a subsequent phase, to the extent necessary.

Defendants estimate that trial on the claims related to Otezla will take approximately 8 days, excluding jury selection, and trial on the claims related to Ozanimod will take approximately 12 days, excluding jury selection.

AMENDMENTS TO THIS PRETRIAL ORDER WILL BE PERMITTED AS THE PARTIES CONTINUE TO PREPARE FOR TRIAL AND TO ACCOUNT FOR RULINGS BY THE COURT THAT POST-DATE THE FILING OF THIS PRETRIAL ORDER.

JBC

NO OTHER AMENDMENTS TO THIS ORDER, APART FROM THOSE NECESSITATED BY SUBSEQUENT COURT RULINGS AND RELATED DEVELOPMENTS, SHALL BE PERMITTED EXCEPT UPON A SHOWING OF MANIFEST INJUSTICE.

/s/ Matthew L. Mustokoff
Matthew L. Mustokoff

/s/ Kevin M. McDonough
Kevin M. McDonough

UNITED STATES MAGISTRATE JUDGE

DATED: 12/19/24

(EXHIBIT LISTS AND DEPOSITION DESIGNATIONS TO FOLLOW)